AMERICAN SOCIETY OF PLASTIC SURGEONS ®
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Northwest Society of Plastic Surgeons

October 30, 2024

The Honorable April Erickson, APRN, *Board of Nursing*
The Honorable Brian Larson, DC, *Board of Chiropractic Examiners*
The Honorable Kenley Michaud, DDS, *Board of Dental Examiners*
The Honorable Eric Nimmo, MD, *State Medical Board*
The Honorable Wendy Palin, *Board of Barbers & Hairdressers*
The Honorable Ashley Schaber, PharmD, *Board of Pharmacy*
Medical Spa Services Work Group
550 West 7th Avenue, STE 1500
Anchorage, AK 99501

RE: Recommendations Regarding "Medical Spa Services"

Dear Members of the Medical Spa Services Work Group:

On behalf of the Northwest Society of Plastic Surgeons (NWSPS) and the American Society of Plastic Surgeons (ASPS), we are writing with recommendations in determining the scope of medical spa services. ASPS is the largest association of plastic surgeons in the world, and in conjunction with NWSPS, represents more than 8,000 members and 92 percent of all board-certified plastic surgeons in the United States – including 20 board-certified plastic surgeons in Alaska. Our mission is to advance the quality of care for plastic surgery patients and promote public policy that protects patient safety.

Our Societies commend the Work Group's commitment to researching aspects related to the oversight, diagnosis, prescription, administration, and follow-up care to statutorily define "medical spa services", but we have concerns surrounding previous discussions regarding aesthetic procedures/modalities.

While laser procedures are extremely safe and effective when used by medical professionals with appropriate training and oversight, they can cause painful burns and permanent scarring in the wrong hands. Even when used at the manufacturer's recommended settings, these devices can cause profound skin injury. For instance, despite only one-third of laser hair removal procedures being performed by non-physicians (including registered nurses (RNs), nurse practitioners (NPs), estheticians, or "technicians"), procedures performed by non-physicians accounted for 76 percent of injury lawsuits from 2002-2012. This number jumped to 85.7 percent of lawsuits filed between 2008-2012, with 64 percent of treatments performed outside of a traditional medical setting.

For patient safety and quality outcomes, it is critical that all lasers and intense pulse light (IPL) devices are only operated by physicians or other licensed medical professionals under direct physician supervision. These licensed professionals include physician assistants (PAs), NPs, and RNs who are acting within the scope of their licensure and are under a physician's supervision. They should not

include estheticians, cosmetologists, or other professionals who have no medical training. Allowing "advanced/master estheticians" to use chemical, mechanical, heat modalities, or a combination of these to perform complex medical procedures that fall squarely within the practice of medicine would be a significant misstep, as it lends credence to the idea that they can and should perform these procedures. They should not.

For non-medical professionals, no amount of training can provide the medical expertise necessary to perform procedures involving lasers or light-based devices. Weekend courses and a written protocol with a provider can never supplement the medical training obtained by RNs, NPs, PAs, or physicians – training which is necessary to identify complications that may arise while performing the laser procedure. Therefore, it would not be appropriate for estheticians, or any other non-medical professional, to perform procedures that could jeopardize patient safety.

With respect to supervision, ASPS recommends the following supervision standards for PAs, NPs, or RNs utilizing lasers: the supervising physician should be properly trained and qualified to perform the procedures being delegated, immediately available by electronic communication, be no further than fifty (50) miles away, and must be available to physically see the patient within twenty-four (24) hours. These supervision requirements recognize that certain physician specialists, like plastic surgeons, are going to be in-hospital performing surgeries on some days, but also provide a mechanism to protect the public from medical spas with physician supervisors in name only.

There are also serious patient risks involved with including cosmetic injectables such as botulinum toxin and fillers within the scope of practice for nonmedical professionals. For example, an injection error of just a few millimeters can result in a punctured eyeball with resulting catastrophic vision loss. Such errors could also result in a perforated blood vessel, which connects to the back of the eye and can cause immediate and permanent vision loss. Another severe risk is misdiagnosing a cancerous lesion as benign, and then improperly injecting it, which can result in the spread of cancer.

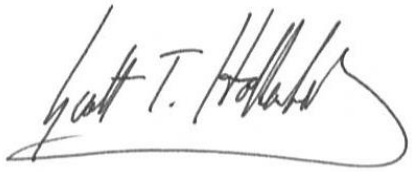
While some injections are intended for cosmetic use, the risk of an injection error noted above still exists. In terms of cosmetic injections, ASPS's policy statement on the administration of botulinum toxin neuromodulators – enclosed for your review – goes into great detail on the background of the development of injecting botulinum toxins and other similar therapies. It took over 30 years of research and development to derive clinical uses of botulinum toxins to treat serious medical conditions, such as cervical dystonias, cranial nerve VII disorders, benign essential blepharospasm, general spasticity, strabismus, migraine headaches, hyperhidrosis, vocal cord dysfunction, anal fissures, urinary incontinence, bruxism, vasospastic disorders of the hand, and other conditions. Botulinum toxins are now an established component of facial rejuvenation.

In fact, we urge you to read a recent North Carolina State Board of Dental Examiners' statement regarding elective cosmetic procedures to further understand the differences in training expectations for dentists. The dental board itself released a position statement that the use of cosmetic facial procedures, drugs, or cosmetic chemical facial enhancement for purely cosmetic applications is *outside* of the appropriate scope of practice for dentistry, as it does not involve the treatment of the

teeth, gums, alveolar process, jaws, maxilla, mandible, or adjacent tissues or structures of the oral cavity.[1]

When developing recommendations to the individual licensing boards, we implore the Work Group to propose that only licensed medical professionals, and those they supervise meeting the appropriate education, training, and professional standards, should perform cosmetic injectables, non-surgical lasers, and procedures and modalities that potentially penetrate below the dermal layer of the skin. Please do not hesitate to contact Joe Mullin, ASPS State Affairs Manager, at jmullin@plasticsurgery.org or (847) 981-5412 with any questions or concerns.

Sincerely,



Scott T. Hollenbeck, MD, FACS
President, American Society of Plastic Surgeons

Shahram Salemy, MD, FACS
President, Northwest Society of Plastic Surgeons

[1] North Carolina State Board of Dental Examiners, Interpretive Statement on Elective Cosmetic Procedures, February 2022.

Original Investigation

Increased Risk of Litigation Associated With Laser Surgery by Nonphysician Operators

H. Ray Jalian, MD; Chris A. Jalian, JD; Mathew M. Avram, MD, JD

IMPORTANCE Controversy exists regarding the role of nonphysicians performing laser surgery and the increased risk of injury associated with this practice.

OBJECTIVE To identify the incidence of medical professional liability claims stemming from cutaneous laser surgery performed by nonphysician operators (NPOs).

DESIGN, SETTING, AND PARTICIPANTS Search of an online national database of public legal documents involving laser surgery by NPOs.

EXPOSURE Laser surgery by nonphysicians.

MAIN OUTCOMES AND MEASURES Frequency and nature of cases, including year of litigation, certification of provider and operator, type of procedure performed, clinical setting of injury, and cause of legal action.

RESULTS From January 1999, to December 2012, we identified 175 cases related to injury secondary to cutaneous laser surgery. Of these, 75 (42.9%) were cases involving an NPO. From 2008 to 2011, the percentage of cases with NPOs increased from 36.3% to 77.8%. Laser hair removal was the most commonly performed procedure. Despite the fact that approximately only one-third of laser hair removal procedures are performed by NPOs, 75.5% of hair removal lawsuits from 2004 to 2012 were performed by NPOs. From 2008 to 2012, this number increased to 85.7%. Most cases (64.0%) by NPOs were performed outside of a traditional medical setting.

CONCLUSIONS AND RELEVANCE Claims related to cutaneous laser surgery by NPOs, particularly outside of a traditional medical setting, are increasing. Physicians and other laser operators should be aware of their state laws, especially in regard to physician supervision of NPOs.

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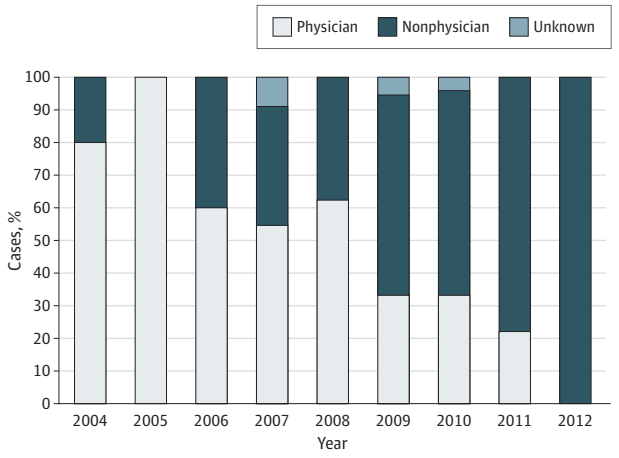
Cutaneous laser surgery remains one of the most popular elective procedures performed in the United States. Among dermatologic surgeons alone in 2011, more than 1.6 million laser treatments were performed.[1] Many more procedures were performed by physicians in other specialties and by nonphysician operators (NPOs). As the numbers of these procedures increase, a concomitant growth has occurred in laser injury-related litigation.[2] The practice of delegation to NPOs has accompanied the burgeoning trend toward greater availability of laser surgery and is hypothesized to be in part responsible for the increase in injury and litigation.[3] Moreover, the past decade saw the massive expansion of the so-called medical spas, nonmedical facilities offering aesthetic and cosmetic procedures.[4] Many of these facilities are owned by or retained by physicians; however, most of the procedures are performed by NPOs of varying certifications as permitted by state regulation. The degree of supervision varies among states, and often the physician supervisor is not required to be on the premises at the time of rendering of services.[5]

Many physicians are increasingly using physician extenders (PEs) within their practice to meet rising demand and falling reimbursements. Among dermatologists, almost 30% reported using a PE within their practice, a 40% increase over the preceding 5 years.[6] Although no data have emerged regarding increased litigation associated with this practice, legal precedence and numerous investigations are clear on liability.[7] When a physician delegates duties to a PE, responsibility and liability remain squarely on the supervising physician provided that the services rendered fall within the scope

Figure. Procedures Performed by Nonphysician Operators Increasingly Represent Most Lawsuits



The percentage of cases involving a nonphysician operator is expressed as a percentage of total operators per calendar year. Note the increasing trend toward a larger proportion of nonphysician operators starting in 2008.

of duty of the PE. This holds true for physician supervision of NPOs in the setting of cutaneous laser surgery.[2]

Despite these trends and clear inconsistencies in state regulations, no study to date has quantified the effect of these practices on medical professional liability claims with regard to cutaneous laser surgery. The objective of this study was to expand on previously published findings in an effort to identify high-risk practices that result in litigation. In addition, the study examines the incidence of litigation related to the performance of laser surgery by NPOs.

Methods

We searched the legal research resource WestlawNext (http://westlaw.com) using various keywords as previously reported.[2] This database is a primary source used by attorneys to gather legal information and is available by subscription to the public. Documents within this database are in the public record. The study was exempt from review, as determined by the institutional review board at Massachusetts General Hospital. An updated search yielded one additional case, bringing the total number of claims concerning injury resulting from cutaneous laser surgery to 175. Of these 175 cases, 75 of the procedures were performed by NPOs. For this study, an *NPO* is defined as a non-MD, non-DO provider. Because of the nature of the documents within the database, it is difficult to ascertain the exact certification of the NPOs. In an effort to be accurate, various allied health professionals comprised the NPO category. This included operators described as a *registered nurse* or a *nurse practitioner*, as well as terms such as *technician*, *aesthetician*, *assistant*, and *intern*. In addition to previously acquired data, the setting where services were rendered was recorded.

Results

NPO as a Function of Year of Litigation

Of 175 cases identified, the first occurrence of an NPO was in 1999. From January 1999, to December 2012, a total of 75 cases with NPOs were identified. This represents 42.9% of the total cases during the same time frame. Stratification of laser operator by year of litigation revealed a striking trend. From 2004 to 2012, a trend was observed toward an increased proportion of lawsuits stemming from cutaneous laser surgery performed by NPOs. This trend is most notable from 2008 to 2011, our most recent data, during which time the percentage of cases involving an NPO increased from 36.3% to 77.8%. Of the 2 cases in 2012, both were performed by an NPO. These results are summarized in the **Figure**.

Procedures

In line with our previously published data,[2] the most commonly performed procedure (n = 40) from 2004 to 2012 that resulted in injury and litigation by an NPO involved laser hair removal. Rejuvenation, composed mainly of intense pulsed light treatments, was the second most commonly litigated procedure (n = 7). Among the NPO cases, a notable trend is evident: when expressing the number of NPO cases as a percentage of the total number of cases for the same procedure, 75.5% of laser hair removal lawsuits from 2004 to 2012 were performed by an NPO. This number is even more dramatic in the years 2008 to 2012, when 85.7% of all laser hair removal lawsuits were performed by an NPO. From 2010 to 2012, a total of 90.0% (18 of 20) of laser hair removal cases were performed by an NPO. The remainder of the litigated procedures by NPOs and the proportion of total cases are given in **Table 1**.

Location of Services

From 1999 to 2012, a total of 64.0% (n = 48) of the NPO cases arose in a nonmedical practice setting. These include medical spas and other nonmedical facilities offering cosmetic services (eg, salons, spas, etc). In 2008 to 2011, NPO procedures performed in medical spas represented almost 80% of lawsuits. Of the 2 cases in 2012, one was performed in a medical spa setting and the other in a physician office. When looking at the type of procedure performed in this setting, most of these cases were laser hair removal procedures. From 2008 to 2012, a total of 68.6% (n = 24) of laser hair removal litigation cases involved an NPO in a medical spa setting. These results are summarized in **Table 2**.

Specific Allegations

Not surprisingly, the injuries sustained following laser surgery by NPOs and the causes of action in these cases mirror those previously reported by our group.[2] However, the specific allegations in these cases offer insight into various liabilities imposed on physician supervisors.

It is necessary to first examine the 2 different forms of liability (direct and vicarious) that a physician could face arising from allegedly improper laser treatment. A physician is directly liable for any negligence that can be attributed to an

Table 1. Cases Involving Laser Procedures Performed by Nonphysician Operators

Procedure	No./Total No. (%) All Cases[a] (n = 106)	All Cases by Nonphysician Operators 2004-2012[b]	All Cases by Nonphysician Operators 2008-2012[b]
Hair removal	40 (37.7)	40/53 (75.5)	30/35 (85.7)
Rejuvenation[c]	7 (6.6)	7/22 (31.8)	7/22 (31.8)
Leg veins	3 (2.8)	3/7 (42.9)	3/7 (42.9)
Vascular[d]	1 (0.9)	1/4 (25.0)	1/4 (25.0)
Tattoo	1 (0.9)	1/4 (25.0)	1/4 (25.0)
Scar	2 (1.9)	2/2 (100.0)	2/2 (100.0)
Pigmented lesion	1 (0.9)	1/1 (100.0)	1/1 (100.0)
Other[e]	2 (1.9)	2/3 (66.7)	2/3 (66.7)

[a] All cases from 2004 to 2012, including physician, nonphysician, and unknown operators.

[b] All nonphysician operator cases expressed as a percentage relative to the total specific procedure cases with all operators.

[c] Most with an intense pulsed light device.

[d] Includes treatment of vascular lesions and telangiectasia.

[e] Includes one case related to fat removal and one case of skin tightening.

Table 2. Setting of Cases Involving Laser Procedures Performed by Nonphysician Operators

Year	No./Total No. (%) Medical Spa	Physician Office	Unknown Setting	Laser Hair Removal[a]
1999-2012	48 (64.0)	25 (33.3)	2 (2.7)	33/48 (68.8)
2004-2012	41 (70.7)	16 (27.6)	1 (1.7)	29/40 (72.5)
2008-2012	36 (76.6)	11 (23.4)	0	24/35 (68.6)

[a] Number of cases performed by nonphysician operators in a medical spa setting relative to the total procedures performed by nonphysician operators in all settings.

individual capacity (ie, the personal failure to perform his or her duties at the requisite standard of care). A physician's duties often extend beyond the laser procedure; for instance, a physician may be directly liable for any negligent hiring, supervision, or training and so forth.

Conversely, a physician is vicariously liable for the negligence of his or her employees. A physician's vicarious liability is rooted in the doctrine of *respondeat superior* (Latin for "let the master answer"). This common law doctrine is often used to hold the employer responsible for the actions of his or her employees if and when the employee is acting within the scope of his or her employment. The rationale underpinning the application of vicarious liability to an employer is 2-fold. First, an employer has the ability and duty to control his or her employees. Second, presumably an employee is performing duties that will result in a benefit to the employer and in so doing is acting under the direction or authority of the employer. Therefore, in a medical malpractice context, a physician can be vicariously liable for the negligence of his or her subordinates, including nurses, NPOs, and other staff.

Almost all of the malpractice cases arising from the negligence of NPOs are coupled with vicarious liability claims against the employer, often a medical spa but at times a physician owner. Notably, 25 of 58 cases (43.1%) with NPOs from 2004 to 2012 represented instances in which no direct physician supervisor was identified. In these cases, the facility was often named as the defendant. As for a physician's direct liability in NPO cases, by far the most common specific allegation (n = 27) was failure to supervise the delegate. Failure to supervise represents the physician's failure to properly oversee the procedure. Failure to train and hire appropriate staff was the second most common specific allegation (n = 23). In addition to these allegations, negligent entrustment (n = 2) was alleged against the physician employers in their individual capacity. Negligent entrustment arises when one party (the entrustor) is held liable for providing another individual (the entrustee) with a potentially dangerous instrument. In this context, a physician can be held liable for providing an NPO with a laser if this instrument is used for a procedure that results in injury to a patient. The physician liability is predicated on the fact that a reasonable person in like circumstances would not have entrusted the NPO with the equipment. A summary of specific allegations (where available) relating to injury sustained as a result of laser surgery by NPOs from 1999 to 2012 includes the following: failure to properly hire, train, or supervise staff (n = 27); failure to properly perform treatment or operate a laser (n = 23); failure to conduct a test spot (n = 10); lack of a license to perform a procedure (n = 6); failure to recognize or treat an injury (n = 5); and negligent entrustment (n = 2). As can be seen from the foregoing definitions, a physician's direct liability is predicated on his or her negligence, not the negligence of his or her employee or agent.

Discussion

Physician delegation of laser surgery has grown significantly during the past decade. In addition, nonphysician-supervised NPO laser surgery is being performed legally in many states at nonmedical facilities. Data on the safety of NPO performance of cutaneous laser surgery are lacking in the medical literature. Most important, a clear trend demonstrates a dramatic increase in the number of lawsuits associated with NPO performance of laser surgery. The NPOs comprise a vast diversity of operators, including nurse practitioners, registered nurses, medical assistants, electrologists, and aestheticians, among others. In 2011, the latest year with a presumed complete data set, 77.8% of the cases involved an NPO. In addition, of the cases with NPOs, almost two-thirds occurred outside of a traditional medical practice. From an examination of

the specific allegations available in this study, the following 2 themes emerged: (1) both vicarious and direct liability of the supervising physician and (2) the prevalence of nonmedical personnel failing to perform procedures commensurate with the standard of care, including recognizing and treating complications.

We propose that the overall trend in increased litigation for laser surgery is in part explained by greater numbers of NPOs performing these procedures, in particular those practicing without direct supervision in the medical spas. This is the first study to date to offer such quantitative evidence. Of the procedures performed, laser hair removal accounted for most of these cases. Indeed, laser hair removal is the most frequently performed laser procedure in the United States.[8] However, if one takes into account the number of procedures performed by operators (physician vs NPO), the data become even more compelling. Only one-third of laser hair removal procedures in 2012 were performed by an NPO; the remaining two-thirds were performed by physicians.[8] Despite the fact that physicians perform most laser hair removal, 85.7% of laser hair removal lawsuits in our study from 2008 to 2012 are cases involving an NPO. In 2011, a remarkable 90.9%% (10 of 11) of laser hair removal litigation was against NPOs. One way to interpret these data is that some increased inherent risk of injury exists with an NPO.

The inconsistency and ambiguity of the state laws exemplify the lack of uniformity of the practice of delegation. For example, in Maine only a physician may operate a laser for hair removal. At the other end of the spectrum, Nevada as of June 2011 had no regulations regarding the use of a laser. In addition to the ability to delegate these procedures is the degree of supervision required. Some state statutes are explicit in stating the need for a written protocol, the requirement to appropriately train and document the training of personnel, and the necessity for adequate supervision. Many physicians "lend" their medical license to these facilities without meeting the legal requirements for supervision. In line with this, California recently passed a bill (California Assembly Bill 1548, Chapter 140) that increases penalties for illegally owning and operating a medical spa, with fines up to $50 000 and a maximum of 2 to 5 years in state prison. The lack of overarching federal law makes it difficult to uniformly require qualifications of personnel allowed to render laser treatments. Despite appropriate certification, regulations regarding appropriate training are ambiguous and are subject to interpretation. Because laws and regulations are constantly evolving, it is imperative for physicians who use PEs to be up to date. Current guidelines can be found at state medical board and state legislature websites.

In the correct setting, with close on-site supervision and appropriate training, the use of NPOs can prove to be a fruitful, productive, and safe environment for patients. Perhaps a larger issue is the role of NPOs, as well as physicians without adequate training, in the operation of a laser. Technology related to laser surgery has evolved rapidly since the description of selective photothermolysis by Anderson and Parrish[9] in 1983. Despite the propagation of nonmedical facilities performing these procedures, the tremendous amount of physics and medicine related to cutaneous surgery should not be overlooked. The American Society for Dermatologic Surgery Association position promulgates the use of energy devices capable of altering or damaging living tissue to physicians who are "trained appropriately in the physics, safety, and surgical techniques involved in the use of energy devices capable of damaging living tissue prior to performing procedures using such devices."[10] Moreover, in the setting of delegation, a physician "should be fully qualified by residency training and preceptorship or appropriate course work prior to delegating procedures to licensed allied health professionals and should directly supervise the procedures. The supervising physician shall be physically present on-site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed."[10] Finally, the position statement underscores the need for "appropriate documented training in the physics, safety, and surgical techniques of each system. The licensed allied health professional should also be appropriately trained by the delegating physician in cutaneous medicine, the indications for such surgical procedures, and the pre- and post-operative care involved in treatment."[10]

Several limitations are inherent in conducting research using a legal database. First, although it is a massive data bank, only one legal database was searched. Cases within the database are those in which some form of legal action was taken and exclude complaints handled outside of the judicial system (ie, third-party arbitration through a malpractice carrier). This is likely to have excluded many frivolous claims with little merit. Second, the query was a retrospective review and was limited by the search terms selected; it is likely that some decisions exist that did not contain the searched terms. Third, these legal pleadings are layman documents (ie, not medical records), and the veracity of the facts was assumed to be true. Furthermore, layman terms may have eluded a database search for the purposes of this study. Fourth, because of the limited number of cases with NPOs for certain procedures, it is difficult to interpret the trends for less commonly performed surgery. Nonetheless, the actual data likely understate the true incidence of NPO laser complications. Generally, plaintiffs' attorneys do not pursue litigation against uninsured operators. Unlike physicians, NPOs (especially in a nonmedical office setting) are less likely to possess liability insurance that can satisfy a potential malpractice or other legal judgment.

A dramatic increase in litigation has been filed against NPOs performing cutaneous laser procedures in medical and nonmedical office settings. This has important implications for the safety of patients undergoing these procedures. When a physician delegates duties to a PE, responsibility and liability remain squarely on the supervising physician provided that the services rendered fall within the scope of duty of the PE. This holds true for physicians supervising NPOs in the setting of cutaneous laser surgery. Given the increase in NPO laser surgery procedures and a parallel trend in greater frequency of lawsuits, further studies are needed to examine this troubling trend in laser safety.

ARTICLE INFORMATION

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Author Contributions: Dr H. R. Jalian had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: H. R. Jalian, Avram.
Acquisition of data: H. R. Jalian, C. A. Jalian.
Analysis and interpretation of data: All authors.
Drafting of the manuscript: All authors.

Conflict of Interest Disclosures: Dr Avram serves as a member of the medical advisory board for Zeltiq Aesthetics, Inc, and of the scientific advisory board for Cytrellis Biosystems, Inc. He has served as a consultant for Unilever, Zeltiq Aesthetics, Inc, and Allergan within the past 12 months. No other disclosures were reported.

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NOTABLE NOTES

The Men or Women Behind Nevi: Alfred Guido Miescher

Fabrizio Vaira, MD; Gianluca Nazzaro, MD; Carlo Crosti, MD; Stefano Veraldi, MD

The man behind Miescher nevus is Alfred Guido Miescher. He was born on November 4, 1887, in Naples, Italy. His mother was Marietta Berner, and his father, Max Eduard Miescher, was a businessman. He was the nephew of Johannes Friedrich Miescher (1844-1895), professor of pathophysiology at the University of Basel, Switzerland, and discoverer of nucleic acids. After the father's death, he followed his mother to Basel, her hometown, where Guido completed his school.

He started his studies in engineering at the *Eidgenössische Technische Hochschule* in Zurich, Switzerland, and then switched to medicine, studying in Basel, Zurich, and Munich, Germany.[1] Working as an assistant of the dermatologist Bruno Bloch, he wrote his thesis on a case of mycetoma. In 1933, after the death of his mentor, Miescher become professor and director of the University Dermatology Clinic in Zurich. Miescher was an excellent clinician, and he was passionate about clinical dermatology and Dermatopathology. Indeed, he said that "Dermatology is more than morphology."[1]

In his original landmark work, *Histologie de 100 cas de naevi pigmentaires d'après les methods de Masson*, published in 1935, Miescher studied 100 hemispherical naevi found mostly on women's' faces. They are dome-shaped papules in which melanocytes are distributed mostly endophytically, often in a wedge, and they reach the deep reticular dermis.[2,3] Miescher was a pioneer in the treatment of skin diseases with phototherapy and of cutaneous tumors with ionizing radiation. Indeed, he helped to improve dermatological radiotherapy, through determining the safest doses and innovative fractionation schemes to reduce the toxic effects. Miescher was skilled in identifying new aspects of already known diseases. He reclassified granulomatosis disciformis chronica et progressiva, and, in 1945, he was the first to describe the cheilitis granulomatosa, subsequently also called Miescher cheilitis.

His students said that he cared about only 3 things: dermatology, music, and mountains. Miescher was a gifted cellist and a lover of mountaineering, as well as an illustrious dermatologist. He bravely climbed numerous Swiss peaks. But his most important venture was an expedition to the Caucasus Mountains. Miescher was the first person to climb Mount Elbrus (5629 m) and ski down. After a life full of medical and sporting achievements, he fought against the cancer and died in 1961.

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AMERICAN SOCIETY OF PLASTIC SURGEONS

POLICY STATEMENT **ADMINISTRATION OF BOTULINUM TOXIN NEUROMODULATORS**

Background

Botulinum toxins are neuromodulators produced from the bacteria of the family Bacillaceae. There are at least seven different serotypes but only type A and type B have clinical applications. Clostridium botulinum, the agent that causes botulism in humans, produces powerful endotoxins which block the release of acetylcholine at the neuromuscular junction, thus inhibiting muscle contraction.[1-2] After over 30 years of research and development, clinical applications include: cervical dystonias, cranial nerve VII disorders (including hemifacial spasm), benign essential blepharospasm, general spasticity, strabismus, migraine headaches, hyperhidrosis, vocal cord dysfunction, anal fissures, urinary incontinence, bruxism, vasospastic disorders of the hand, and other conditions. Botulinum toxins are now an established component of facial rejuvenation.

The first FDA approval of Botulinum Toxin Type A, produced as Botox® ®, was in 1979 for treatment of strabismus. FDA approval followed in 2002 for Botox Cosmetic® to temporarily improve the appearance of moderate to severe frown lines between the eyebrows (glabellar lines)[3] and in 2013, for treatment of periorbital rhytides ("crow's feet").

As FDA actions for botulinum toxins are expected to increase, plastic surgeons should check to make sure they are up to date on the latest approvals. Any non-approved use is considered off-label.

As of 2016, FDA approved Botulinum Toxin Type A is available from three manufacturers:

- Botox®and Botox Cosmetic® (OnabotulinumtoxinA, manufactured by Allergan, Irvine, CA)
- Dysport® (abobotulinumtoxinA, manufactured byIpsen Ltd., Berkshire UK)
- Xeomin® (incobotulinumtoxinA manufactured by Merz Pharmaceuticals, Frankfurt, Germany)

FDA approved Botulinum Toxin Type B is available as Myobloc® (rimabotulinumtoxinB, Solstice Neurosciences, San Francisco, CA).

Other forms of Botulinum Toxin Type A and Type B are available worldwide but are NOT FDA approved and therefore not available in the United States. For purposes of this document, further discussion will be limited only to the three FDA approved Botulinum Toxin Type A (BTA): Botox Cosmetic®, Dysport®, and Xeomin®.

The biologic activities of the three BTA products are more similar than different but according to the FDA, they should not be considered interchangeable. For example, the number of units used for a clinical indication cannot be directly compared, as, 10 units of Botox Cosmetic or Xeomin applied to a particular facial region may require 20 to 30 units of Dysport to achieve similar clinical effects. Additionally, the onset and duration of clinically evident effects may also not be the same. BTA typically requires 7 to 10 days to see full effects and the results last 3 to 4 months. Patient may be re-evaluated 2 weeks after an injection to determine if more treatment is needed. A more detailed clinical comparison of BTA products and applications is available.[4]

Clinical decisions about the use of a drug are the purview of the physician.

Complications

Potential transient adverse local effects include but are not limited to: rash, pain, edema, erythema, ecchymosis, headache or hyperesthesia at the injection site. These are not necessarily related to the drug. There has also been a single report of a localized anaphylaxis in the lower limb following injection for foot dystonia.[5] Systemic complications may include flu-like symptoms or distant skin rashes.[6] There has also been one report of a respiratory arrest following the use of botulinum toxin type A for muscle spasticity.[7] Other rare but more frequently reported events are adverse or undesirable soft tissue effects that relate mostly to technique and result in temporary soft tissue malposition (such as blepharoptosis, brow ptosis, cheek ptosis, and lower eyelid ectropion or retraction, etc.) Care should be used in the periocular region as temporary upper and lower eyelid dysfunction may occur. In the event of upper eyelid ptosis after BTA injection, alpha 2-adrenergic agonist eye drops may be used to treat the ptosis.

Patients may develop non-responsiveness to BTA injections. This may be related to antibody formation but the specific mechanisms are not yet known.

Patient Selection

Not all individuals are candidates for BTA injections. Among those who should not receive such injections are those who are sensitive to the ingredients; patients with neuromuscular diseases (such as myasthenia gravis, Eaton-Lambert syndrome, or amyotrophic lateral sclerosis); and pregnant (also lactating/breast feeding) women. Injections should be applied with caution and discretion in those patients on anticoagulation/aspirin therapy; patients treated with aminoglycosides, penicillamine, quinine, or calcium channel blockers, as these drugs have been known to possibly potentiate clinical effects.[8,9] Patients who have unreasonable expectations or psychological issues that would preclude a satisfactory outcome should be excluded from treatment. Patients should understand that the effect of botulinum treatment can last several months but will not achieve a permanent change nor will it produce the same effect as surgical facial rejuvenation, including facelift. Surgical options should be considered if a more extensive change and longer-term result is desired.

Provider Qualifications

Despite the popularity and safety of BTA, it must be remembered that injection of BTA is a medical procedure. Patients are advised to have treatments with a qualified physician who understands neuromuscular and facial anatomy, facial aging and aesthetics, as well as potential neurotoxicity of the product. Under certain circumstances determined by the physician and applicable local and state professional practice regulations, injections may be administered by a licensed professional nurse or physician assistant. The individual physician of record, however, is ultimately responsible for both understanding and abiding by the applicable local and state professional practice regulations in determining the supervisory involvement required in each situation.

Risk Management Considerations

The injection of BTA is a medical procedure and is subject to the same precautions of any medical procedure. Treatment should be administered in the physician's office or other clinical setting with appropriate medical personnel and necessary equipment to safely observe patients and deal with possible complications. As with any medical procedure, a complete patient record should be maintained. Patients should be fully informed as to the temporary nature of botulinum injections, the risks, benefits, alternatives and reasoning for the proposed treatment as well as off-label uses. Each patient should sign an informed consent statement. Patient photographic documentation before starting treatment may be useful. The medical record should indicate the lot number, dosage, injection sites and any noted adverse reaction of any kind. Documentation of adverse events should include reporting of such incidents to the manufacturer when applicable. Patients should have continuing access to the provider and be medically supervised for several weeks following treatment, should an adverse event occur. Disposal of medical waste should be handled in accord with Occupational Safety and Health Administration (OSHA) regulations.

Although extremely unlikely, epinephrine or other precautionary methods should be available to treat anaphylactic reactions. Signs and symptoms of overdose may not be immediately apparent, but treatment should be initiated immediately when an overdose is realized.[10]

Most BTA injections are done in a physician's office but may also be done in a medical spa setting without a physician on site. State and local laws need to be followed in such cases. BTA injections in non-clinical settings (private homes, work events, group or social gatherings) may be inappropriate for several reasons, which include:

- inadequate patient selection by the provider
- inadequate individualized informed consent
- possible peer pressure for an individual to consent to treatment
- providers who are not trained in the administration of botulinum or qualified to assess or treat complications

The decision to have a medical procedure should be made without the influence of alcohol or peer pressure. If BTA is administered outside of a clinical setting, care should be taken to provide an appropriate environment for each patient and assure the same level of patient selection and informed consent as in a clinical environment.

Ethical Considerations

The Code of Ethics of the American Society of Plastic Surgeons states that a member may be subject to disciplinary action, including expulsion, if the member participates in a charity raffle, fund raising event, contest or other promotion in which the prize is any procedure.[11] For purposes of the Code of Ethics, BTA is NOT considered a medical procedure. However, the most current version of the Code should be reviewed prior to any such offering.[12]

Conclusion

BTA injections can be a safe and effective temporary treatment of fine facial lines and wrinkles, can produce a temporary improvement of facial and periorbital shape, and can serve as a useful adjunct in a variety of plastic surgical procedures.[13-14] Patients are advised to have treatments with a physician, or a provider designated by the physician, who is trained to give the injections and assess post- treatment effects. Board-certified plastic surgeons are ideally qualified to administer these injections because of their training.

Originally Approved by the American Society of Plastic Surgeons, Executive Committee, June 11, 2002.
Updated and reaffirmed: June 2016

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American Society of Plastic Surgeons

▶ **PRACTICE REFERENCE**

Issued December 15, 2023

Appropriate Business and Clinical Management of Medical Spas

Summary: Medical spas offer a variety of cosmetic treatments, including medical procedures. Because these procedures can pose certain safety risks for patients, the delivery of this care should involve proper physician oversight and supervision. Thus, the American Society of Plastic Surgeons (ASPS) has developed a ***practice reference*** to (1) inform the appropriate business and clinical management of medical spas and (2) provide state policymakers with benchmarks for policies that protect patient safety.

BACKGROUND

Medical spas, sometimes referred to as "medi-spas" or "med spas," combine some medical procedures normally performed in a doctor's office with the experience of a day spa. They offer non-invasive treatments, including cosmetic procedures, with a focus on looking younger and healthier.

Medical spas are often led by physician directors, many with plastic surgery or dermatology backgrounds. However, some are operated by physicians from other specialties or even non-physicians, such as nurse practitioners or other mid-level providers, raising safety concerns.[1–4] Requirements for medical spa ownership and supervision, and medical practice management more broadly, vary by state.[5]

RATIONALE

Medical spas are of interest to ASPS because they offer not only cosmetic *non-medical* procedures but also cosmetic *medical* procedures[6]—which stimulate, alter, or destroy living tissue. Treatments considered medical include procedures such as hair transplants, cosmetic soft tissue fillers, cosmetic injections, and numerous energy-based treatments.

Cosmetic medical procedures pose certain safety risks. They require practitioners to have adequate training to perform them effectively and, most critical, manage any complications that may arise. Thus, any facilities offering these services should adhere to appropriate business and clinical management principles to provide patients with the highest quality care.

This document does not explicitly address liability issues, but the suggested approaches are meant to protect patient safety and, in turn, could support risk management.

▶ REFERENCE

for Surgeons

ASPS has developed a practice reference for the optimal business and clinical management of a medical spa in order to help ensure that structural elements are in place to optimize safety and quality. **Members should consider how they may abide by these principles in the context of their state's statutes and regulations that directly or indirectly govern supervision in medical spas.**

For example, many states have policies that reflect the "corporate practice of medicine doctrine," which prohibits corporations from practicing medicine.[7] These policies often bar non-physicians from owning medical practices or employing physicians. In addition, states may have statutes or regulations with requirements for virtual supervision or telemedicine consults that could apply to medical spas. Another aspect of state law that should be considered is the differing levels of independence granted by states to certain mid-level practitioners.

Role of the Medical Director

ASPS has identified several considerations specific to the qualifications and responsibilities of the medical director in a medical spa. The Society believes optimal state regulations would follow these considerations. In a neutral context, where existing state laws are not a consideration, the medical director should—

Qualifications

- Be a physician licensed to practice medicine in the state where the facility operates.

- Have the proper education, training, experience, and competence to safely administer, delegate, and supervise each cosmetic medical procedure at the medical spa. This includes completion of an Accreditation Council for Graduate Medical Education (ACGME)-accredited residency in a medical specialty that provides complete training in the procedures performed at the medical spa.

Responsibilities

- Accept responsibility for the safety of all patients treated at the medical spa.
- Establish a means for obtaining the appropriate informed consent from each patient prior to treatment.
- Develop and sign written protocols for any cosmetic medical procedure that may be performed at the medical spa.
- Ensure that all physicians or non-physician practitioners are trained and qualified to perform the procedures with which they are tasked—including certification for the use of specific equipment—and assess their clinical performance.
  - Procedures using a Food and Drug Administration (FDA)-cleared or FDA-regulated device should be performed only by an appropriately trained physician or by appropriately trained non-physician personnel under the direct supervision of an appropriately trained physician.
  - FDA-regulated drugs should be prescribed only by an appropriately trained physician or by appropriately trained non-physician personnel under the direct supervision of an appropriately trained physician.
- Ensure that licensed medical professionals, such as nurse practitioners, physician assistants, registered nurses, licensed vocational nurses, and licensed practical nurses, comply with their professional scope of practice and act in accordance with their respective state licensing boards.
- Confirm that the medical spa is equipped with all necessary equipment, supplies, and processes to address medical complications and emergencies that may arise during treatment.
- Understand and abide by all applicable local and state statutes and regulations.

Role of the Supervising or Delegating Physician

The supervising or delegating physician at a medical spa may be the medical director or any physician at the facility who delegates tasks or procedures to non-physicians. In the absence of an identified medical director, the supervising or delegating physician assumes the additional responsibilities of a medical director.

ASPS has also identified considerations specific to the qualifications and responsibilities of the supervising or delegating physician in a medical spa. The Society believes optimal state regulations would follow these considerations. In a neutral context, where existing state laws are not a consideration, the supervising or delegating physician should—

Qualifications

- Have the proper education, training, experience, and competence to safely administer, delegate, and supervise each cosmetic medical procedure at the medical spa. This includes completion of an ACGME-accredited residency in a medical specialty that provides complete training in the procedures they are performing, supervising, or delegating at the medical spa.

Responsibilities

- Accept responsibility for the safety of all patients whose treatment they supervise.
- Ensure that appropriate informed consent is obtained from each patient prior to treatment.
- Provide necessary supervision, according to state-specific requirements and the physician's professional judgement, over each cosmetic medical procedure performed under the physician's supervision at the medical spa.
- Ensure that all practitioners under the physician's supervision are trained and qualified to perform the procedures with which they are tasked—including certification for the use of specific equipment, such as FDA-cleared or FDA-regulated devices.
- Delegate only those medical procedures that are in the physician's area of expertise and within the statutory or regulatory scope of the profession of the non-physician practitioner performing the procedures.
- When delegating procedures to a non-physician practitioner, maintain ultimate responsibility for the patient's care. This may include conducting an initial evaluation for each new patient to establish the appropriate diagnosis and treatment plan.
- When supervising or delegating minimally invasive cosmetic medical procedures by non-physicians, remain within 50 miles or 1 hour of travel time from the facility and remain immediately available for consultation during the procedure.

- Understand and abide by all applicable local and state statutes and regulations.

▶ REFERENCE

FOR POLICYMAKERS

States have an opportunity to implement policies that ensure appropriate clinical supervision and optimal practice in medical spas. States should consider the following principles[8] when developing policies aimed at improving patient safety for these entities:

- Codify a definition of "surgery" and a definition of "cosmetic medical procedure." Procedures by any means, methods, devices, or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue constitute the practice of medicine and surgery. These include but are not limited to the use of scalpels; all lasers and light sources, microwave energy, electrical impulses, and all other energy-emitting devices; thermal destruction; chemical application; particle sanding; and other foreign or natural substances by injection or insertion.
- Specify that any procedure that constitutes the practice of medicine, including any procedure using an FDA-cleared or FDA-regulated device that can alter or cause biologic change or damage, should be performed only by an appropriately trained physician or by appropriately trained non-physician personnel under the direct supervision of an appropriately trained physician.
- Mandate that medical spa facilities be licensed and inspected on a regular basis to ensure compliance with all applicable federal and state statutes and regulations.
- Provide requirements to ensure transparency and truthful advertising:
  - A medical director of a medical spa facility should be clearly identified as the medical director in all marketing materials and websites related to the medical spa facility, and all such communications should also list the medical director's licensure, ACGME/American Osteopathic Association (AOA)-trained medical specialty, and American Board of Medical Specialties (ABMS)/AOA board certification.
  - If marketing materials mention a physician's board certification, the certifying board and specific specialty should also be stated (e.g., Diplomate of the ABMS in Dermatology). States should implement restrictions on the use of non-ABMS or AOA boards in advertising, as many have insufficient standards for securing diplomate status.
  - The medical director must ensure that marketing and advertising materials of a medical spa facility do not include false, misleading, or deceptive representations.
  - Non-physicians must wear identification that displays their provider type and licensing.
- Set standards for the qualifications of personnel performing procedures or managing the medical spa:
  - Any physician or non-physician personnel who provides a cosmetic medical procedure must be qualified to (1) perform such procedures by virtue of having received appropriate theoretical and clinical instruction and training in each service to be performed—including safety, clinical application, and pre- and post-procedural care—and (2) handle any resultant emergencies or sequelae.
  - Any licensed physician or non-physician employed by a medical spa, including a medical director, must have received appropriate documented training and education in the safe and effective performance of all cosmetic medical procedures performed in the facility.
- Require that deaths and significant complications be reported to the state for investigation:
  - Any incident within the medical spa facility that results in a patient death, transport of the patient to the hospital for observation or treatment for a period of more than 24 hours, or a significant complication or adverse event requiring additional medical treatment must be reported to the state within a time frame that aligns with the state's guidelines for adverse event reporting. Such reports should be investigated by the appropriate state entity.
  - Any adverse events involving the use of FDA-cleared or FDA-regulated devices must be reported to the FDA in accordance with federal statutes and regulations.
- Specify that the state's board of medical examiners must establish and maintain an online registry for medical spas and a continuous process for monitoring and inspecting facilities for compliance.

This document was approved for distribution by the ASPS Medical Spa Task Force on September 15, 2023; the ASPS Healthcare Delivery Committee on October 4, 2023; and the ASPS Board of Directors on December 8, 2023.

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Esthetics Procedures Continuum DRAFT – December 2024

This document does not reflect any decisionmaking by an Alaska professional licensing work group or board. This document is a working draft and does not define current Alaska requirements.

This chart may be used in whole or in part to assist the Alaska Medical Spa Services Work Group and related Alaska professional licensing boards understand the procedures in question, as well as assist in clarifying current and future scope of practice of:

- **Currently licensed estheticians** under the Board of Barbers and Hairdressers
- Future **advanced esthetician** licensees (requires statute change)
- Persons performing these procedures under **medical supervision:** In the context of this document, "medical supervision" means on-site supervision by a physician, physician assistant, or APRN operating within the supervisor's scope of practice and all statutes and regulations pertaining to the supervisor's license. May be currently allowable or require statute or regulation change to clarify necessary training and education.

Numbering refers to additional information available in the Esthetics Procedures List, available on the Medical Spa Services Work Group website: https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/MedicalSpaServicesWorkGroup.aspx

Can currently be performed under the existing 350-hour Alaska esthetician license	**Recommend statute to require continuing education under existing 350-hour license**	**Recommend statute to require additional training as part of a 900+ hour advanced esthetician license (no medical supervision)**	**Currently requires medical supervision of any delegated duties**
ACTION REQUESTED: Clarify in regulation (currently proposed by Board of Barbers and Hairdressers)	**ACTION REQUESTED:** Board of Barbers and Hairdressers work on legislative proposal	**ACTION REQUESTED:** Medical Board, Board of Nursing, and Board of Barbers and Hairdressers collaborate on legislative proposal	**ACTION REQUESTED:** Medical Board and Board of Nursing clarify in regulation and in white paper
EFFECT OF ACTION: Licensed estheticians will understand what procedures they may perform under their current license	**EFFECT OF ACTION:** Public safety will be increased; estheticians may continue to perform these services while being held accountable for training	**EFFECT OF ACTION:** Highly trained estheticians can perform limited advanced esthetics services without medical supervision	**EFFECT OF ACTION:** Persons supervising, delegating, and performing these services will have clarity on expectations; public safety and awareness will be increased
1. Ultrasonic devices Epidermis Impact: Superficial **2. Oxygen Concentrator devices** Epidermis Impact: Superficial **3. Electrotherapy devices (galvanic current, High Frequency)** Epidermis Impact: Superficial **4. Mechanical brush devices** Epidermis Impact: Superficial **5. Vacuum spray devices** Epidermis Impact: Superficial **6. Steamers** Epidermis Impact: Superficial **7. LED (light emitting diode) devices.** Epidermis Impact: Superficial/Light **8. Microcurrent devices** Epidermis Impact: Superficial **9. Microdermabrasion devices, including hydradermabrasion devices.** Epidermis Impact: Superficial **10. Skin analysis equipment** Epidermis Impact: None **11. Thalassotherapy (application of sea water)** Epidermis Impact: Superficial **12. Thermotherapy (application of heat), manually applied or with the use of devices.** Epidermis Impact: Superficial	**3. Electrotherapy devices (galvanic current, high frequency)** Epidermis Impact: Superficial **9. Microdermabrasion devices, including hydradermabrasion devices.** Epidermis Impact: Superficial **13 & 14. Superficial and light chemical exfoliation; alpha hydroxy acids, beta hydroxy acids, modified Jessner solutions, trichloroacetic acid less than 20% and vitamin based acids.** Epidermis Impact: Superficial at lower concentrations **15. Low-level ultrasound devices (Sonophoresis)** Epidermis Impact: Superficial **17. Class 2 radiofrequency devices** Epidermis Impact: Medium **22. Dermaplaning devices*** Epidermis Impact: Superficial **24. Collagen induction device (microneedling) including microchanneling or nanostamp below 1mm, not OTC devices*** Epidermis Impact: Superficial **(NEW) Semi-permanent hair removal** by nonablative IPL *Requires correction of definition in AS 08.13.220	**13 & 14. Medium chemical exfoliation** including higher-level concentrations, Jessner solutions and TCA Epidermis Impact: Medium **16. HIFU (High Intensity Focused Ultrasound)** Epidermis Impact: Superficial: Medium Dermis Impact: Deep	**13 & 14. Deep chemical exfoliation** Epidermis Impact: Deep **18. Class 3 laser and radiofrequency devices other than hair removal** Epidermis Impact: Medium Dermis Impact: Deep **19. Lipolysis** Dermis Impact: Deep **24. Collagen induction device (microneedling) above 1.0mm** Dermis Impact: 1.5mm-2.5mm **(NEW) Cosmetic injectables:** Prescription drugs intended to treat wrinkles, lines, and other cosmetic complaints, such as botulinum toxin (Botox) and other neuro-modulators, hyaluronic acid gel (Juvederm), calcium hydroxylapatite (Radiesse), polylactic acid (Sculptra) **(NEW) Semi-permanent hair removal** by ablative laser

13 & 14. Superficial and light chemical exfoliation; alpha hydroxy acids, beta hydroxy acids, modified Jessner solutions, trichloroacetic acid less than 20% and vitamin based acids. Epidermis Impact: Superficial at lower concentrations **15. Low-level ultrasound devices (Sonophoresis)** Epidermis Impact: Superficial **17. Class 2 radiofrequency devices** Epidermis Impact: Medium **19. Cryotherapy (application of cold, not lipolysis), manually applied or with the use of devices.** Epidermis Impact: Superficial **20. Hydrotherapy** Epidermis Impact: Superficial **21. Cellulite appearance and contouring treatments (creams, wraps, etc.)** Epidermis Impact: Superficial **22. Dermaplaning devices*** Epidermis Impact: Superficial **23. Mechanical stimulation (facial massage)** Epidermis Impact: Superficial/Medium **(NEW) Semi-permanent hair removal** by nonablative IPL *Requires correction of definition in AS 08.13.220			