

# Report to the General Assembly

An Act Concerning the Department of Public Health's Oversight Responsibilities relating to Scope of Practice Determinations:

Scope of Practice Review Committee Report on Electrologists

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## State of Connecticut

# Department of Public Health

# Report to the General Assembly

An Act Concerning the Department of Public Health's Oversight
Responsibilities relating to Scope of Practice Determinations for Health Care
Professions

# **Table of Contents**

xecutive Summary	3
Background	4
icope of Practice Request	5
mpact Statements and Responses to Impact Statements	3
scope of Practice Review Committee Membership	6
Scope of Practice Review Committee Evaluation of Request	6
Description of How the Request Relates to the Profession's Ability to Practice to the Full Extent of the	
Profession's Education and Training	. 10
indings and Conclusions	
IIIUIIIKS and Conclusions	

#### **Executive Summary**

In accordance with Public Act 11-209, the Connecticut State Electrologists Association (CSEA) submitted a scope of practice request to the Department of Public Health to change the scope of practice for licensed electrologists. CSEA specifically requested to expand the scope of practice of licensed electrologists to include the removal of hair through the use of laser or light devices. A scope of practice review committee was established to review and evaluate this request as well as subsequent written responses to the request and additional information that was gathered through the review process.

The "practice of electrology" is currently defined in Connecticut law as the permanent removal of superfluous hair by electrical of other methods approved by the Commissioner of Public Health. Laser hair removal is a procedure in which the laser beam passes through the skin to an individual hair follicle and damages the follicle, which inhibits future hair growth. Although laser hair removal effectively slows hair growth, it is not considered permanent hair removal. Equipment currently used to perform laser hair removal is classified as a "medical device" by the U.S. Food and Drug Administration (FDA) and use of these machines is considered the practice of medicine in Connecticut. Under current state law, laser hair removal may only be performed by a physician or by a licensed nurse or physician's assistant who is working directly with a physician.

While there are many states including Connecticut that do not allow electrologists or licensed/regulated professionals other than physicians, nurses and physician assistants to perform laser hair removal, several states allow physicians to delegate laser hair removal procedures to electrologists or other regulated professions such as cosmetologists, estheticians, laser hair removal technicians, or laser hair practitioners. There are also a small number of states that allow electrologists or others to perform laser hair removal through a consultative relationship with a physician. In the states where a physician may delegate laser hair removal to electrologists or other professionals, state laws and/or regulations specify the types of devices that may be used and the necessary level of physician supervision/involvement, as well as particular education, training and certification requirements. Some of these states also regulate the facility where the laser hair removal procedures are being performed. In most of these states, the requirements are not specific to electrologists and apply to any non-physician who is authorized to perform laser hair removal procedures.

Under the scope of practice request submitted by the CSEA, licensed electrologists with at least three years of experience who complete thirty hours of additional coursework in the use of laser and light-based hair removal or reduction devices would be authorized to independently perform laser hair removal procedures using any laser approved by the FDA for hair removal, without the supervision or involvement of a licensed physician. CSEA contends that "by continuing to prohibit electrologists from performing laser hair removal procedures the profession is not allowed to grow and that opponents have not successfully documented why electrologists should not be able to perform laser. Yet, while the CSEA was able to demonstrate that the number of licensed electrologists has considerably diminished over the last several years, CSEA did not provide documented evidence to support their position that electrologists can safely engage in laser hair removal procedures as outlined in their proposal.

Scope of practice review committee members repeatedly requested additional clarifying information from the CSEA, including but not limited to, identifying: the specific types of lasers electrologists would use (e.g., typically hair reduction or removal uses non-ablative lasers but the proposal was not specific); the types and doses of medications including topical anesthetics that the electrologists intend to dispense and/or administer in conjunction with laser hair removal procedures; and the specific requirements related to education, training and certification as well as mandatory malpractice insurance coverage. At least one of the physician members of the scope of practice review committee acknowledged that appropriately trained individuals could probably perform laser hair removal safely with physician oversight and requested CSEA to reconsider their position on physician involvement.

CSEA stipulated throughout the process that they are not interested in pursuing a model that would require electrologists to be supervised by or consult with a physician to perform laser hair removal. They cited reasons including their belief that medical supervision is being proposed to "create a barrier to entry to lasers" and that mandating physician oversight and/or involvement is too expensive and would lead to higher costs for patients. In response to the committee's request for clarifying information, CSEA submitted a completely revised scope of practice request; however, the revised request was not submitted within a time frame that would have provided the scope of practice review committee with sufficient time to review the request and respond. Upon initial review by the Department, although the revised request includes information concerning the history of electrolysis and laser hair removal, more specific information regarding the performance of laser hair removal in other states and an increase in the number of hours in the proposed curriculum; the other significant concerns identified by scope of practice review committee members were not addressed.

The documentation provided in support of this request did not adequately address the quality and safety concerns raised by scope of practice review committee members associated with allowing licensed electrologists to engage in laser hair removal without physician oversight. Additional concerns regarding whether the proposed education and training requirements would prepare an electrologist to safely and effectively practice laser hair removal were also not addressed. Data to support that this proposal has the potential to enhance access to quality and affordable health care in Connecticut was not provided. Electrologists are already practicing to the full level of their current education and training as aligned with the existing scope of practice.

#### Background

Public Act 11-209, <u>An Act Concerning the Department of Public Health's Oversight Responsibilities</u>

<u>Relating to Scope of Practice Determinations for Health Care Professions</u>, established a process for the submission and review of requests from health care professions seeking to revise or establish a scope of practice prior to consideration by the General Assembly. Under the provisions of this act, persons or entities acting on behalf of a health care profession that may be directly impacted by a scope of practice request may submit a written impact statement to the Department of Public Health. The Commissioner of Public Health shall, within available appropriations, establish and appoint members to a scope of

practice review committee for each timely scope of practice request received by the Department. Committees shall consist of the following members:

- Two members recommended by the requestor to represent the health care profession making the scope of practice request;
- Two members recommended by each person or entity that has submitted a written impact statement, to represent the health care profession(s) directly impacted by the scope of practice request; and
- 3. The Commissioner of Public Health or the commissioner's designee, who shall serve as an exofficio, non-voting member of the committee.

The Commissioner of Public Health was also authorized to expand the membership of the committee to include other representatives from other related fields if it was deemed beneficial to a resolution of the issues presented.

Scope of practice review committees shall review and evaluate the scope of practice request, subsequent written responses to the request and any other information the committee deems relevant to the scope of practice request. Such review and evaluation shall include, but not be limited to, an assessment of any public health and safety risks that may be associated with the request, whether the request my enhance access to quality and affordable health care and whether the request enhances the ability of the profession to practice to the full extent of the profession's education and training. Upon concluding its review and evaluation of the scope of practice request, the committee shall provide its findings to the joint standing committee of the General Assembly having cognizance of matters relating to public health. The Department of Public Health (DPH) is responsible for receiving requests and for establishing and providing support to the review committees, within available appropriations.

#### Scope of Practice Request

The Connecticut State Electrologists Association (CSEA) submitted a scope of practice request to the Department of Public Health to change the scope of practice for licensed electrologists. CSEA specifically requested to expand the scope of practice of licensed electrologists to include the removal of hair through the use of laser or light devices upon successful completion of a further course of study as required by the Connecticut Board of Examiners of Electrologists and approved by Department of Public Health.

#### Impact Statements and Responses to Impact Statements

Written impact statements in response to the scope of practice request submitted by the CSEA were received from the Connecticut State Medical Society, the Connecticut Dermatology and Dermatalogic Society, the Connecticut Society of Eye Surgeons, the Connecticut Society of Plastic and Reconstructive Surgeons and the American Academy of Ophthalmology. Overall, these organizations do not support the proposed scope of practice change. Although additional correspondence regarding this scope of

practice request was received by the Department from other individuals, the correspondence was not in the form of a written impact statement, did not provide specific documentation to support or refute the proposal and was submitted after the statutory deadline for submission of written impact statements had passed. As such, these documents were not reviewed by the scope of practice review committee. CSEA submitted a written response to the impact statement that was submitted by the Connecticut Society of Plastic and Reconstructive Surgeons, which was provided to the scope of practice review committee members for review.

## Scope of Practice Review Committee Membership

In accordance with the provisions of Public Act 11-209, a scope of practice review committee was established to review and evaluate the scope of practice request submitted by the CSEA. Committee members included representation from:

- 1. The Connecticut State Medical Society;
- 2. The Connecticut Dermatology and Dermatologic Society;
- 3. The Connecticut Society of Eye Surgeons;
- 4. The Connecticut Society of Plastic and Reconstructive Surgeons;
- 5. The American Academy of Ophthalmology; and
- 6. The commissioner's designee (chairperson and ex-officio, non-voting member).

## Scope of Practice Review Committee Evaluation of Request

CSEA's scope of practice request included all of the required items identified in PA 11-209 as outlined below. Additional clarifying information was requested during the review and evaluation of this request.

#### Health & Safety Benefits

CSEA identified the following health and safety benefits associated with implementing the proposed scope of practice change:

Laser hair removal/reduction technology permits the treatment of a given area of the body much more rapidly than electrolysis and has become extremely popular with the public. At present in Connecticut the use of these devices is limited to a licensed physician or delegation to a physician's assistant or licensed nurse pursuant to a December 17, 1997 Declaratory Ruling by the Connecticut Medical Examining Board. Typically this equipment is used by personnel with limited training under the general supervision of a physician, usually a dermatologist, in clinics and spas. The large pool of licensed and skilled electrologists who have considerable experience in body and facial hair removal

through the use of electrolysis equipment are presently unable to lawfully operate laser hair removal equipment. If the request is implemented, a large experienced and trained pool of professionals will augment the existing providers thereby improving the overall quality of delivery of laser hair reduction services.

Documented evidence to support the health and safety benefits for clients associated with the performance of laser hair removal by electrologists was not provided. Articles and other medical literature regarding the dangers and complications of laser therapy, especially the head and neck areas were provided by other members of the scope of practice review committee. It is important to note that while this literature highlights the inherent risks associated with the use of lasers, it does not specifically target electrologists and is relevant for any professionals who engage in the use of lasers for hair removal. More importantly however documents stress inherent peril of narrowly focused knowledge and training as opposed to broad and deep knowledge of human anatomy, physiology function, surgical therapy and pathology.

#### Access to Healthcare

CSEA identified that implementation of the scope of practice request would have the following impact on public access to health care:

Although some hair removal demand is cosmetically driven, in many cases there is health or medical reasons for hair removal. These have traditionally been handled by electrologists by referral from physicians. In some instances laser devices may have speed advantages over traditional electrolysis in treatment of these conditions. Increasing the number of professionals who can utilize laser and light based hair removal/reduction equipment will help meet the increasing demand by the public for these services. Displacing some of the demand for hair removal from medical spas and clinics and other licensed health care professionals to electrologists will increase the availability of dermatologists and other licensed medical personnel working under their supervision for treatment of other medical and skin disorders. Anecdotal evidence suggests that the demand for hair removal has increased the waiting time to obtain consultations with medical professionals in Connecticut.

Documented evidence to support the statements made by the CSEA with regard to impact on access to health care was not provided.

#### Laws Governing the Profession

#### As identified by CSEA:

The profession of electrology and the use of electrolysis equipment (which is regulated by the FDA) are typically regulated at the state level. States including New York and Pennsylvania have chosen not to regulate it at all. In others there is minimal regulation focused on sterilization of needles and proper disposal of blood contaminated objects or it is regulated as a cosmetology profession. In the majority of jurisdictions it is regulated as a profession under the state department of business or professional regulation (e.g., Illinois and Vermont) or as in the majority of states who regulate it as a

healing/allied health profession under the supervision of the state's health department (e.g., Connecticut, Rhode Island, Massachusetts, Maine, New Hampshire and Florida).

Electrologists are currently regulated by the Department of Public Health and the Board of Examiners of Electrologists pursuant to Connecticut General Statutes, Chapter 388 and the Regulations of Connecticut State Agencies, Sections 20-269-3 through 20-275b-7, inclusive.

#### Current Requirements for Education and Training and Applicable Certification Requirements

In order to become licensed in Connecticut, an electrologist must have graduated from a program that is approved by the Board of Examiners of Electrologists with the consent of the Department of Public Health and includes:

- (A) At least two hundred hours of classroom instruction in basic sciences applicable to electrology, including but not limited to: bacteriology, sanitation and hygiene, biology, dermatology, trichology, theory of electricity, electrolysis and principles of infection control; and
- (B) At least four hundred hours of practical instruction in epilation techniques, utilizing electrolysis (direct current/DC) and thermolysis (alternating current/AC) modalities.

Applicants for licensure are also required to successfully complete a national written licensure examination and a Connecticut practical examination. All licensed electrologists must complete a minimum of ten contact hours of qualifying continuing education each year, at least two hours of which shall be in infection control, blood borne diseases, universal precautions or sanitation and sterilization, any combination thereof. Some electrologists go on to earn the Certified Professional Electrologist (CPE) credential which is offered by the American Electrology Association. The CPE credential is not a requirement to practice in Connecticut.

#### Summary of Known Scope of Practice Changes

In 2009, House Bill 5616 was referred to the Public Health Committee but no public hearings were held and the bill did not move forward.

#### Impact on Existing Relationships within the Health Care Delivery System

CSEA indicated in its scope of practice request that no impact is anticipated between electrologists and physicians and other licensed health professionals working under their supervision who currently deliver laser hair removal services. Opponents of the proposal disagree with the CSEA's position in that the use of lasers for hair removal currently falls under the scope of practice of medicine. Therefore, allowing electrologists to engage in laser hair removal would require a change to the medical practice act and would impact physicians.

#### **Economic Impact**

CSEA identified that implementation of the scope of practice request would have the following economic impact on the health care delivery system:

A large number of physicians and other licensed health care professionals under their immediate supervision are currently delivering laser and light based hair removal services. There continues to be a strong public demand for unwanted facial or body hair reduction/removal through the use of laser and light based technology and hair removal/reduction is only one of the several uses for laser equipment. The typical laser equipment training session delivered to physicians and their staff at present lasts an evening or a day and covers all dermatologic uses of the manufacturer's particular equipment in addition to laser hair removal. Electrologists have considerable more training and experience with hair removal and its complications and contraindications than most of those health professionals currently permitted to operate this equipment. Electrologists envision that by increasing the size and quality of the pool of professionals that can perform laser hair removal/reduction will be in the public interest as advanced medical or surgical training is unnecessary to the safe and effective deliver of laser hair removal services. Electrologists also believe that by increasing their scope of practice and allowing their profession to perform laser hair removal, it may enhance access by the public to physicians who are currently "quite busy supervising the delivery of cosmetic procedures of hair reduction". The electrologists also believe that adding some of the approximately 165 licensed electrologists in the state to the pool of professionals who can perform laser and light based hair reduction/removal should assure price stability for these services or possible even reduce cost.

Documented evidence to support the statements made by the CSEA with regard to economic impact was not provided.

#### **Regional and National Trends**

CSEA did not identify any specific regional or national trends related to the practice of electrology and laser hair removal. While there are many states including Connecticut that do not allow electrologists or licensed/regulated professionals other than physicians, nurses and physician assistants to perform laser hair removal, several states allow physicians to delegate laser hair removal procedures to electrologists or other regulated professions such as cosmetologists, estheticians, laser hair removal technicians, or laser hair practitioners. There are also a small number of states that allow electrologists or others to perform laser hair removal through a consultative relationship with a physician. In the states where a physician may delegate laser hair removal to electrologists or other professionals, state laws and/or regulations specify the types of devices that may be used and the necessary level of physician supervision/involvement, as well as particular education, training and certification requirements. Some of these states also regulate the facility where the laser hair removal procedures are being performed. In most of these states, the requirements are not specific to electrologists and apply to any non-physician who is authorized to perform laser hair removal procedures.

# <u>Description of How the Request Relates to the Profession's Ability to Practice to the Full Extent of the Profession's Education and Training</u>

CSEA provided the following description of how the scope of practice request relates to the profession's ability to practice to the full extent of their education and training:

Electrologists have been academically and practically trained in several of the areas needed to operate laser hair removal equipment, including but not limited to, the biology of hair, basic electricity, skin typing, side effects of epilation, pre-treatment patient preparations, treatment contraindications including the recognition of disease conditions of the skin, post treatment procedures, expected outcomes including erythema and edema, the nature of possible adverse outcomes, follow-up care, completion of patient intake forms and proper documentation of patient case history and consent forms. Failure to promptly extend to electrologists the ability to use laser and light based devices for hair removal or reduction will impede the profession's ability to practice the profession and will deprive the residents of Connecticut better access to professional hair removal services.

Documented evidence to support the statements made by the CSEA with regard to impact on access to health care was not provided. Coursework in the use of laser and light-based hair removal or reduction devices is not currently included within curriculum that is required to become licensed as an electrologist in Connecticut and would need to be developed. Electrologists are already practicing to the full level of their current education and training as aligned with the existing scope of practice.

#### Findings and Conclusions

The scope of practice review committee reviewed and evaluated all of the information provided in the CSEA's scope of practice request as well as additional information that was provided as a result of committee discussions. Additional clarifying information and documentation requested by the scope of practice review committee was not provided by CSEA to support the proposed changes. In reviewing and evaluating the information presented, the scope of practice committee focused on assessing any public health and safety risks associated with the request, whether the request may enhance access to quality and affordable health care and whether the request enhances the ability of the profession to practice to the full extent of the profession's education and training.

The "practice of electrology" is currently defined in Connecticut law as the permanent removal of superfluous hair by electrical of other methods approved by the Commissioner of Public Health. Laser hair removal is a procedure in which the laser beam passes through the skin to an individual hair follicle and damages the follicle, which inhibits future hair growth. Although laser hair removal effectively slows hair growth, it is not considered permanent hair removal. Equipment currently used to perform laser hair removal is classified as a "medical device" by the U.S. Food and Drug Administration (FDA) and use of these machines is considered the practice of medicine in Connecticut. Under current state law, laser hair removal may only be performed by a physician or by a licensed nurse or physician's assistant who is working directly with a physician.

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Department, although the revised request includes information concerning the history of electrolysis and laser hair removal, more specific information regarding the performance of laser hair removal in other states and an increase in the number of hours in the proposed curriculum; the other significant concerns identified by scope of practice review committee members were not addressed.

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### **Appendices Table of Contents**

Appendix A Scope of Practice Law

Appendix B Committee Membership

**Appendix C** Original Scope of Practice Request

Appendix D Impact Statements

**Appendix E** Regulations Governing Electrologists

**Appendix F** Proposed Curriculum for Electrologist Performing Laser

**Appendix G** ASDSA Summation of Chart & Map

Appendix H Complications from Laser Procedures Performed by Non-

physicians

Appendix I Medical Spas are the New Litigation Hot Spot, Attorneys

Say.

Appendix J Adverse Events Associated with Nonablative Cutaneous

Laser, Radiofrequency and Light-Based Devices

Appendix K Ocular Complications of Laser-Assisted Eyebrow Epilation

Appendix L Iritis and Pupillary Distortion after Periorbital Cosmetic

Alexandrite Laser

Appendix M Iris Atrophy and Posterior Synechiae as a Complication of

**Eyebrow Laser Epilation** 

Appendix N Diode-laser-induced Cataract and Iris Atrophy as a

Complication of Eyelid Hair Removal

# Appendix A



#### Substitute House Bill No. 6549

#### Public Act No. 11-209

AN ACT CONCERNING THE DEPARTMENT OF PUBLIC HEALTH'S OVERSIGHT RESPONSIBILITIES RELATING TO SCOPE OF PRACTICE DETERMINATIONS FOR HEALTH CARE PROFESSIONS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2011*) (a) Any person or entity, acting on behalf of a health care profession that seeks to establish a new scope of practice or change a profession's scope of practice, may submit a written scope of practice request to the Department of Public Health not later than August fifteenth of the year preceding the commencement of the next regular session of the General Assembly.

- (b) (1) Any written scope of practice request submitted to the Department of Public Health pursuant to subsection (a) of this section shall include the following information:
- (A) A plain language description of the request;
- (B) Public health and safety benefits that the requestor believes will be achieved should the request be implemented and, if applicable, a description of any harm to public health and safety should the request not be implemented;
- (C) The impact that the request will have on public access to health care;
- (D) A brief summary of state or federal laws that govern the health care profession making the request;
- (E) The state's current regulatory oversight of the health care profession making the request;
- (F) All current education, training and examination requirements and any relevant certification requirements applicable to the health care profession making the request;
- (G) A summary of known scope of practice changes either requested or enacted concerning the health care profession in the five-year period preceding the date of the request;
- (H) The extent to which the request directly impacts existing relationships within the health care delivery system;

- (I) The anticipated economic impact of the request on the health care delivery system;
- (J) Regional and national trends concerning licensure of the health care profession making the request and a summary of relevant scope of practice provisions enacted in other states;
- (K) Identification of any health care professions that can reasonably be anticipated to be directly impacted by the request, the nature of the impact and efforts made by the requestor to discuss the request with such health care professions; and
- (L) A description of how the request relates to the health care profession's ability to practice to the full extent of the profession's education and training.
- (2) In lieu of submitting a scope of practice request as described in subdivision (1) of this subsection, any person or entity acting on behalf of a health care profession may submit a request for an exemption from the processes described in this section and section 2 of this act. A request for exemption shall include a plain language description of the request and the reasons for the request for exemption, including, but not limited to: (A) Exigent circumstances which necessitate an immediate response to the scope of practice request, (B) the lack of any dispute concerning the scope of practice request, or (C) any outstanding issues among health care professions concerning the scope of practice request can easily be resolved. Such request for exemption shall be submitted to the Department of Public Health not later than August fifteenth of the year preceding the commencement of the next regular session of the General Assembly.
- (c) In any year in which a scope of practice request is received pursuant to this section, not later than September fifteenth of the year preceding the commencement of the next regular session of the General Assembly, the Department of Public Health, within available appropriations, shall: (1) Provide written notification to the joint standing committee of the General Assembly having cognizance of matters relating to public health of any health care profession that has submitted a scope of practice request, including any request for exemption, to the department pursuant to this section; and (2) post any such request, including any request for exemption, and the name and address of the requestor on the department's web site.
- (d) Any person or entity, acting on behalf of a health care profession that may be directly impacted by a scope of practice request submitted pursuant to this section, may submit to the department a written statement identifying the nature of the impact not later than October first of the year preceding the next regular session of the General Assembly. Any such person or entity directly impacted by a scope of practice request shall indicate the nature of the impact taking into consideration the criteria set forth in subsection (b) of this section and shall provide a copy of the written impact statement to the requestor. Not later than October fifteenth of such year, the requestor shall submit a written response to the department and any person or entity that has provided a written impact statement. The requestor's written response shall include, but not be limited to, a description of areas of agreement and disagreement between the respective health care professions.

- Sec. 2. (NEW) (Effective July 1, 2011) (a) On or before November first of the year preceding the commencement of the next regular session of the General Assembly, the Commissioner of Public Health shall, within available appropriations allocated to the department, establish and appoint members to a scope of practice review committee for each timely scope of practice request submitted to the department pursuant to section 1 of this act. Committees established pursuant to this section shall consist of the following members: (1) Two members recommended by the requestor to represent the health care profession making the scope of practice request; (2) two members recommended by each person or entity that has submitted a written impact statement pursuant to subsection (d) of section 1 of this act, to represent the health care professions directly impacted by the scope of practice request; and (3) the Commissioner of Public Health or the commissioner's designee, who shall serve as an ex-officio, nonvoting member of the committee. The Commissioner of Public Health or the commissioner's designee shall serve as the chairperson of any such committee. The Commissioner of Public Health may appoint additional members to any committee established pursuant to this section to include representatives from health care professions having a proximate relationship to the underlying request if the commissioner or the commissioner's designee determines that such expansion would be beneficial to a resolution of the issues presented. Any member of such committee shall serve without compensation.
- (b) Any committee established pursuant to this section shall review and evaluate the scope of practice request, subsequent written responses to the request and any other information the committee deems relevant to the scope of practice request. Such review and evaluation shall include, but not be limited to, an assessment of any public health and safety risks that may be associated with the request, whether the request may enhance access to quality and affordable health care and whether the request enhances the ability of the profession to practice to the full extent of the profession's education and training. The committee, when carrying out the duties prescribed in this section, may seek input on the scope of practice request from the Department of Public Health and such other entities as the committee determines necessary in order to provide its written findings as described in subsection (c) of this section.
- (c) The committee, upon concluding its review and evaluation of the scope of practice request, shall provide its findings to the joint standing committee of the General Assembly having cognizance of matters relating to public health. The committee shall provide the written findings to said joint standing committee not later than the February first following the date of the committee's establishment. The committee shall include with its written findings all materials that were presented to the committee for review and consideration during the review process. The committee shall terminate on the date that it submits its written findings to said joint standing committee.
- Sec. 3. (NEW) (Effective July 1, 2011) On or before January 1, 2013, the Commissioner of Public Health shall evaluate the processes implemented pursuant to sections 1 and 2 of this act and report to the joint standing committee of the General Assembly having cognizance of matters relating to public health, in accordance with the provisions of section 11-4a of the general statutes, on the effectiveness of such processes in addressing scope of practice

requests. Such report may also include recommendations from the committee concerning measures that could be implemented to improve the scope of practice review process.

Approved July 13, 2011

# Appendix B

#### **Electrologists Scope of Practice Committee Members**

Jennifer Filippone, Department of Public Health
Wendy Furniss, Department of Public Health
Jennifer Lefkowski, Department of Public Health
Philip Kerr, MD, Connecticut State Medical Society
David Emmel, MD; Connecticut Society of Eye Physicians
Gary Price, MD;
Patrick Felice, MD;
Christopher Rossetti, Observing Attorney
Jayne Romero, MD; Licensed Electrologist
Karen Kolenda, Connecticut State Electrology Association
Marta Cuminotto, Connecticut State Electrology Association
Donna Crump, Connecticut State Electrology Association
Lina Haralambous, Licensed Electrologist
David Evans, ETA
Deborah Osborne

# Appendix C

#### CONNECTICUT STATE



August 15, 2011 Hand Delivery

Department of Public Health
Attn: Jennifer L. Filippone, Chief
Practitioner Licensing and Investigations Section
410 Capitol Avenue, MS#12MQA
P.O. Box 340308
Hartford, CT 06134

Re: Scope of Practice Request Connecticut State Electrologists Association

Dear Ms. Filippone,

Please find enclosed Scope of Practice Request on behalf of the Connecticut State Electrology Association.

Should you have any questions concerning the enclosed please do not hesitate to contact me at (860) 678-1972 or our lobbyist, David J.D. Evans, Esq. at (860) 522-3343.

Thank you in advance for your assistance with processing this request.

Very truly yours,

Donna Crump, President

DC/cjr Encls. as above

#### Scope of Practice Request Submission

#### Connecticut State Electrology Association

8-15-2011 (Revised)

1. a plain language description of the request;

To expand the scope of practice of licensed electrologists to include the removal of body and facial hair through the use of laser or light-based devices cleared by the U.S. Food & Drug Administration upon successful completion of a further course of study as required by the Connecticut Board of Examiners of Electrologists and approved by Department of Public Health.

public health and safety benefits that the requestor believes will occur if the request is implemented and, if applicable, a description of any harm to public health and safety if it is not implemented;

In 1997 the FDA began clearing laser devices for permanent hair reduction. The variety and efficacy of these devices has increased over the past 15 years. Laser hair removal/reduction technology permits the treatment of a given area of the body much more rapidly than electrolysis and so has become extremely popular with the public. At present in Connecticut the use of these devices is limited to a licensed physician or by delegation to any person rendering service as a physician's assistant licensed pursuant to section 20-12b, a registered nurse or a licensed practical nurse as defined in subdivision (15) of section 19a-175, acting within the scope of regulations adopted pursuant to section 19a-179, if such service is rendered under the supervision, control and responsibility of a licensed physician per a December 17, 1997 Declaratory Ruling of the Connecticut Medical Examining Board and Connecticut Attorney General's Opinion 2004-15. Typically this equipment is utilized by personnel with limited training under the general supervision of a physician, usually a dermatologist, in clinics and med spas. The large pool of licensed and skilled electrologists who have considerable experience in body and facial hair removal through the use of electrolysis equipment are presently unable to lawfully operate laser hair removal equipment. If the request is implemented a large,

experienced and trained pool of professionals will augment the existing providers improving overall quality of delivery of laser hair reduction services.

#### 3. the impact on public access to health care;

Although some hair removal demand is cosmetically driven, in many cases there are health or medical reasons for hair removal. These have traditionally been handled by electrologists by referral from physicians. In some instances laser devices may have speed advantages over traditional electrolysis in treatment of these conditions. Increasing the number of professionals who can utilize laser and light based hair removal/reduction equipment will help meet the increasing demand by the public for these services. Displacing some of the demand for hair removal from medical spas and clinics and other licensed health care professionals to electrologists will increase the availability, all things being equal, of dermatologists and other licensed medical personnel working under their supervision for treatment of other medical and skin disorders. Anecdotal evidence suggests that the demand for hair removal has increased the waiting time to obtain consultations with medical professionals in Connecticut.

#### 4. a brief summary of state or federal laws governing the profession;

The profession of electrology and the use of electrolysis equipment (which is regulated by the US FDA), is typically regulated at the state level. Some states have chosen not to regulate it at all (e.g. New York and Pennsylvania). In others there is minimal regulation focusing on sterilization of needles and proper disposal of blood contaminated objects (e.g. Washington). In some it is regulated as a cosmetology profession (e.g. California) but in the majority of jurisdictions it is regulated as a profession under the state department of business or professional regulation (e.g. Illinois and Vermont) or, as in the majority of states who regulate it, as a healing/allied health profession under the supervision of the state's health department (e.g. Connecticut, Rhode Island, Massachusetts, Maine, New Hampshire and Florida.)

#### 5. the state's current regulatory oversight of the profession;

In Connecticut electrology is regulated as a profession under Chapter 388 of the Connecticut General Statutes, Sections 20-267 et seq. Chapter 22 provides for the establishment of a five

member Board of Examiners of Electrologists which advises the Commissioner of the Department of Public Health on matters pertaining to the profession and with the consent of the Commissioner establishes minimum requirements for certification. The Board by statute consists of a dermatologist, two electrologists and two lay persons. For initial licensure the passing of a written and practical examination is necessary. The board hears and decides matters concerning suspension or revocation of licensure; adjudicates complaints against practitioners; and imposes sanctions where appropriate. The causes for which a license may be revoked or suspended or for which a practitioner may be the subject of disciplinary action include: (1) Conviction, either within or without this state, of any crime in the practice of the practitioner's profession; (2) fraudulent or deceptive conduct in the course of professional services or activities or illegal, incompetent or negligent conduct, in the practitioner's practice; (3) habitual intemperance in the use of alcoholic liquor or addiction to the use of narcotics or other habit-forming drugs; (4) violation of any provision of this chapter or of any regulation adopted under this chapter; (5) aiding or abetting the unlawful practice of electrology; (6) physical or mental illness or emotional disorder or loss of motor skill of the practitioner, including, but not limited to, deterioration through the aging process; (7) fraud or material deception in obtaining a license; or (8) splitting of fees or offering of commissions or gifts. The Commissioner of Public Health may order a licensee to submit to a reasonable physical or mental examination if the physical or mental capacity of the licensee to practice safely is the subject of an investigation. The commissioner may petition the superior court for the judicial district of Hartford to enforce such order.

All current education, training, and examination requirements and any relevant certification requirements applicable to the profession;

In order for a professional education program to be utilized by an applicant for licensure, it must meet the following requirements: The curriculum shall include the following: (A) At least two hundred hours of classroom instruction in basic sciences applicable to electrology, including but not limited to: bacteriology, sanitation and hygiene, biology, dermatology, trichology, theory of electricity, electrolysis and principles of infection control and (B) At least four hundred hours of practical instruction in epilation techniques, utilizing electrolysis (direct current/DC) and thermolysis (alternating current/AC) modalities. Programs shall be individually reviewed and approved by the Board of Examiners of Electrology with the consent of the Department of Public Health. The program shall submit such materials as may be required to the Board and Department for the purpose of review and approval. Once licensed each licensee applying for license renewal shall have completed a minimum of ten contact hours of qualifying continuing education during the preceding registration period, at least two of which shall be in infection control, blood borne diseases, universal precautions or sanitation and sterilization, or any combination thereof. Continuing education contact hours completed in one registration period shall not carry over to a subsequent registration period.

7. a summary of known scope of practice changes requested or enacted concerning the profession in the five years preceding the request;

In 2009 General Assembly Bill 5616 was referred to the Joint Committee on Public Health but no public hearings were held.

8. the extent to which the request directly affects existing relationships within the health care delivery system;

No impact is anticipated between electrologists and physicians or other licensed health professionals working under their supervision who currently deliver laser hair removal services.

9. the anticipated economic impact on the health care delivery system;

A large number of physicians and other licensed health care professionals under their immediate supervision are currently delivering laser and light based hair removal services. There continues to be a strong public demand for unwanted facial or body hair reduction/removal through use of laser and light based technology. Hair removal/reduction is only one of the several uses for laser equipment.

The typical laser equipment training session delivered to physicians and their staff at present lasts an evening or a day and covers all dermatologic uses of the manufacturer's particular equipment which may include laser treatment of pigmentation, redness, wrinkles, spider veins, benign epidermal pigmented lesions (such as age spots, sunspots and freckles), unwanted tattoos, scars, cellulite, body fat, psoriasis, vitiligo, warts, and the many and sundry types of skin surgery.

Electrologists have considerably more training and experience with hair removal and its complications and contra-indications than most of those health professionals currently permitted to operate this equipment.

Increasing the size and quality of the pool of professionals who can perform laser hair removal/reduction will be in the public interest as advanced medical or surgical training is unnecessary to the safe and effective delivery of laser and light based hair removal services. It may allow better access by the public to physicians who are currently quite busy supervising the delivery of cosmetic which include laser and light based hair reduction.

Adding some of the approximately 185 registered electrologists in the state to the pool of professionals who can perform laser and light based hair reduction/removal should tend to assure price stability for these services or possibly even reduce their cost.

10. regional and national trends concerning licensing of the health profession making the request and a summary of relevant scope of practice provisions enacted in other states;

According to the FDA the popularity of laser and light based hair removal/reduction has grown significantly since its introduction in 1997, prompting many laser manufacturers to conduct research and seek FDA clearance for their lasers for hair reduction uses. The market for this equipment is growing so quickly that the FDA states it cannot maintain an up-to-date list of all laser manufacturers whose devices have been cleared for hair removal. Initially training in the use of the equipment was provided exclusively by the manufacturer. The quality, duration and nature of the training varied widely within the industry. Many states have recently reviewed or are in the process of reviewing their approach to regulation of this new technology.

New England/New York Region: New York does not appear to have acted as of the date of this submission to regulate the use of laser hair removal equipment. It appears that clinics have arisen under the supervision or control of each entrepreneurs, physicians, cosmeticians, aestheticians, electrologists and others. In Pennsylvania the State Board of Medicine has attempted to restrict laser hair removal equipment's use to physicians and those under their immediate supervision. Vermont recently broadened its definition of electrology to include the use of laser equipment by licensed and "properly trained" electrologists. In Massachusetts electrologists are permitted to use laser hair removal equipment but may do so only in a separate area distinct from their electrolysis office. Cosmetologists and aestheticians are permitted to use IPL devices. Recently its legislature has granted to its health department the authority to regulate the use of hair removal lasers. It is expected that it will extend to licensed electrologists, inter alia, the authority to use such equipment after completing a course of training yet to be developed has been approved by the department. Connecticut, Rhode Island, New Jersey and Maine have not as yet addressed the matter. New Hampshire has recently positively defined the use of laser hair removal equipment to constitute "surgery" thus apparently limiting its use to licensed physicians and surgeons or their employees.

#### National Trends:

There does not appear to be a national trend as of this writing. Some states have declined to act in this field. Others like Florida and Illinois have recently adopted regulatory schemes permitting electrologists and other allied health professionals to use laser hair removal equipment after a course of training but under the off-site supervision of a physician. California has authorized only physicians, nurses and physician's assistances to utilize laser

hair removal equipment. Texas Dept. of Health Services permits anyone after an approved course of study and apprenticeship to become a laser hair removal professional and operate a laser hair removal facility provided they obtain a written off premises supervision contract with a consulting physician.

#### International Trends:

The United Kingdom and the European Union permit non-medical personnel, such as beauticians, to perform laser hair removal, but they are legally required to register with the Department of Health's Care Quality Commission to ensure that minimum training and safety standards are met.

Canada does not regulate laser hair removal. Health Canada states in a consumer advisory about cosmetic laser treatments (which includes laser hair removal) that "experts in cosmetics with proper training in laser techniques should be able to perform hair reduction treatments with minimal risks to the Canadian public." Laser hair removal providers need only comply with rules governing personal services establishments.

11 identification of any health care professions that can reasonably be anticipated to be directly affected by the request, the nature of the impact, and efforts made by the requestor to discuss it with such health care professions;

The pool of people that currently operates laser hair removal equipment in Connecticut includes physicians, RN's, LPN's, and PA's under their supervision. A preliminary meeting was held in 2010 with representatives of the Connecticut State Medical Society Dermatology Committee.

12.a description of how the request relates to the health care profession's ability to practice to the full extent of the profession's education and training.

As laser hair removal equipment has improved in its efficacy it has become increasingly apparent to both Connecticut residents and electrologists that laser and light based hair reduction/removal equipment possesses speed and cost advantages over traditional electrolysis/thermolysis for epilation. The speed and efficacy of laser hair removal techniques has had a distinct economic impact on the practice of electrology in the state as many hair reduction/removal candidates are opting for laser treatment instead of electrolysis. As sometimes both electrolysis and laser methods of hair removal will complement one another and use of both would be indicated, extending the authority to use laser hair removal

equipment to electrologists will have further advantages for the patient permitting him or her to be treated by one professional for all types of hair removal services. Electrologists have been academically and practically trained in several of the areas one using laser hair removal equipment should have knowledge: the biology of hair, basic electricity; skin typing, side effects of epilation, pre-treatment patient preparations, treatment contra-indications including the recognition of disease conditions of the skin, post-treatment procedures, post treatment instructions to patients, expected outcomes including erythema and edema, the nature of possible adverse outcomes, follow-up care, completion of patient intake forms, and proper documentation of patient case history and consent forms.

Failure to extend promptly to electrologists the ability to use laser and light based devices for hair removal or reduction will impede their ability to practice their profession and will deprive the residents of Connecticut better access to professional hair removal services.

# Appendix D



#### The Connecticut Society of Plastic & Reconstructive Surgeons, Inc.

September 30, 2011

Jennifer L. Filippone, Chief Practitioner Licensing and Investigations Section Department of Public Health 410 Capitol Ave, MS#12MQA PO BOX 340308 Hartford, CT 06134

Re: Ct Society of Plastic and Reconstructive Surgeons (CSPRS) Impact Statement on Scope of Practice Request from CT State Electrology Association

Dear Jen:

In response to the Scope of Practice request of the CT State Electrology Association, the CSPRS has prepared the following impact statement for consideration by the department. Please do not hesitate to contact me with any additional questions.

All the best,

Lisa Winkler Co-Executive Director

Tricia Dinneen Priebe Co-Executive Director

#### CT Society of Plastic & Reconstructive Surgeons, Inc. Impact Statement

#### 1. A plain language description of the request.

The CT State Electrology Association has filed a request to modify the scope of practice of licensed electrologists in the state to include the use of lasers in the removal of body and facial hair. In the interest of patient safety, the CT Society of Plastic & Reconstructive Surgeons (CSPRS) urges the Department of Public to deny this request.

# 2. Public health and safety benefits, and if applicable, a description of any harm to public health and safety if it is not implemented.

The CSPRS sees no health and safety benefits of expanding the scope of electrologists in this state. In fact, quite to the contrary we see a potential negative impact on safety and quality of care if this scope of practice change is approved.

Lasers are advanced medical devices that are capable of serious, and potentially disfiguring, complications if operated improperly, including blindness, permanent scarring, infections, and permanent discoloration of the skin.

#### 3. The impact of the request on public access to care.

A ruling by the CT Medical Examining Board found that the use of a laser to remove hair is a medical, not a cosmetic procedure which actually alters the surface of the skin. With this in mind, we must seriously consider the impact on the public good. Simply because there is demand for a service does not mean we should expand who is able to provide that service-in this case, a medical procedure. The potential complications are serious and should not be taken lightly.

#### 4. A brief summary of state and federal laws governing the profession.

New York is the only state that explicitly exempts hair removal from the practice of medicine and does so based on a 1937 court case. It should be noted that discussion are underway to establish new regulations in this area. With respect to other states:

- 37 states expressly prohibit electrologists from performing laser hair removal without some form of medical supervision.
- 12 states prohibit electrologists from performing laser hair removal under any circumstances.
- 14 states require on-site medical supervision for laser hair removal to be performed by electrologists.
- · 11 states require an initial medical examination and off-site medical supervision.

#### 5. The state's current regulatory oversight of the profession.

As stated above, in 1997, the CT Medical Examining Board issued a declaratory ruling found that the use of a laser to remove hair is a medical, not a cosmetic procedure that actually alters the surface of the skin and must be performed by a physician.

As such, Section 20-9 of the C.G.S. governs who may practice medicine. (a) No person shall, for compensation, gain or reward, received or expected, diagnose, treat, operate for or prescribe for any injury, deformity, ailment, or disease, actual or imaginary, of another person, nor practice surgery, until he has obtained such a license as provided in section 20-10, as amended, and then only in the kind or branch of practice stated in such license.

Additionally, Section 20-267 of the C.G.S. establishes a definition for the "Practice of electrology." It should be noted that according to the American Electrology Association, to be licensed in CT, you need to be 18 years old with a high school diploma or equivalent, 15 weeks of education, and certification by the IBEC.

6. All current education, training, and examination requirements and any relevant certification requirements applicable to the profession.

Because laser hair removal is considered a medical procedure, appropriate medical training should be required and should include an extensive understanding of cutaneous medicine and surgery, the indications for such surgical procedures, the pre and post operative care involved in treatment, as well as the treatment for any potential complications. Current electroloy training is not sufficient to meet these requirements independently.

7. A summary of known scope of practice changes requested or enacted concerning the profession in the preceding 5 years.

Over the past few years, similar proposals have been introduced in the Public Health Committee but did not enjoy sufficient support for approval.

8. The extent to which the request directly affects existing relationships within the health care delivery system.

By removing the physician from this relationship and allowing electrologists to provide laser treatment, we are threatening the safety and wellbeing of our patients. It is that relationship that is of utmost concern.

9. The anticipated economic impact of the request on the health care delivery system.

The potential for complications-like burning and scarring-is real and the resulting treatment could strain an already overburdened health care delivery system. Medical decisions need to be made before laser treatment is provided. Are there

contraindications to the procedure, pre-existing medical conditions that would place the patient at risk, who is going to treat a patient if a complication occurs?

10. Regional and national trends in licensing of the health profession making the request and a summary of relevant scope of practice provisions enacted in other states.

As discussed in question 4 above:

New York is the only state that explicitly exempts hair removal from the practice of medicine and does so based on a 1937 court case. It should be noted that discussion are underway to establish new regulations in this area. With respect to other states:

- 37 states expressly prohibit electrologists from performing laser hair removal without some form of medical supervision.
- 12 states prohibit electrologists from performing laser hair removal under any circumstances.
- 14 states require on-site medical supervision for laser hair removal to be performed by electrologists.
- · 11 states require an initial medical examination and off-site medical supervision.
- 11.Identification of any health care professions that can reasonably be anticipated to be directly affected by the request, the nature of the impact, and efforts made by the requestor to discuss it with such health care professions.

Plastic surgeons may see an increase in patients with complications as a result of this change.

12.A description of how the request relates to the health care profession's ability to practice to the full extent of the profession's education and training.

According to the American Electrology Association, to be licensed in CT, you need to be 18 years old with a high school diploma or equivalent, 15 weeks of education, and certification by the IBEC. For the reasons detailed above, it would seem that this request is far beyond the 15 weeks training required to be licensed as an electrologist in this state.

# Impact Statement of the Connecticut Society of Eye Physicians and The American Academy of Ophthalmology concerning the Scope of Practice Request of the Connecticut State Electrology Association

The Connecticut State Electrology Association has filed a request "to expand the scope of practice of licensed electrologists to include the removal of body and facial hair through the use of laser or light-based devices cleared by the U.S. Food & Drug Administration upon successful completion of a further course of study as required by the Connecticut Board of Examiners of Electrologists and approved by Department of Public Health." The Connecticut Society of Eye Physicians (CSEP) and the American Academy of Ophthalmology (AAO), as stakeholders in this issue, respectfully request that in the interest of patient safety, this request be denied.

Ophthalmology has a rich and lengthy experience with laser therapy, and welcomes the opportunity to share that experience with the health care community in the context of this proposed scope expansion. Laser surgery was pioneered by ophthalmologists who sought a better way to treat and prevent angle closure glaucoma, one of the most severe and destructive forms of this disease. The ruby laser, and shortly thereafter the argon laser were developed to burn holes in the iris, doing with light what heretofore required a dangerous open surgical procedure. Since then the use of lasers in ophthalmology has expanded rapidly, as it has in other fields, including dermatology where laser is used for a variety of procedures that include but are not limited to hair removal.

Although the course of this expansion was rapid for ophthalmology, where the mostly transparent structures are particular amenable to the transmission of laser light energy, it was not without mishaps along the way. The evolution of technique included many instances of tissue burns, hemorrhages, and scarring many of which involved some degree of blindness, and all of these still occur today, although the incidence of such complications has been significantly reduced. We perceive a sense among our patients that laser surgery is safe and harmless, and FDA endorsements of both over-the-counter and medical grade laser products suggest that as well. However, medical grade lasers are powerful surgical instruments and are anything but harmless if they are not wielded with great care and expertise.

In contrast to laser therapy, the technique currently employed by electrologists involve one at a time destruction of hair follicles at the root using by thermolysis where the dispersion of energy is focal and the risk of adjacent tissue damage is small. Because standard electrolysis is focal, treating just along the hair follicle, it is in a certain sense applied "around" the skin. Laser energy, on the other hand, must pass through all layers of the skin where it is absorbed even before it reaches the more deeply situated hair follicles. And it can be applied broadly over large expanses of skin. Moreover the use of medical grade lasers for hair removal requires the use of strong topical anesthetics with all of the attendant risks inherent to the administration of anesthesia, including death.

It stands to reason that the errors and mishaps that can and do occur with laser hair removal treatments are likely to be considerably more widespread and potentially more serious than when treatment proceeds follicle to follicle. Laser hair removal complications may not seem as disabling as that which occurs with laser treatments of the eye, but the scarring and pigmentary changes that occur with complicated skin treatments are almost always in areas of skin that are exposed to view. This can have a profound effect on the patient's sense of well-being especially when the treatment was intended to produce a cosmetic improvement.

Above all, we recognize that the safe use of medical lasers is more than a matter of reading a manual and following the instructions on a piece of equipment. The forethought and planning before a procedure even begins is ultimately what determines the outcome of the laser procedure. Many of these ophthalmic laser procedures seem quick and easy, over nearly as soon as they have begun, even as permanent changes are made to the patient's eye or skin. Much of the skill comes from knowing where, when and how to apply laser energy, as well as what to do when something goes wrong. Laser technology is a rapidly evolving field and the devices and modalities that are in place today may be gone tomorrow, making it all the more necessary to have a fundamental knowledge of the physical and biological processes that underlie the destructive tissue transformations that form the basis of this unique and valuable form of surgical treatment.

It is our belief that all surgical techniques, whether by scalpel or laser light energy, demand the lengthy and rigorous training programs that only physicians receive. Patient safety is most likely to be preserved and quality outcomes achieved when these high standards are strictly adhered to. Successful surgery requires preparation, execution, and the handling of postoperative care including the management of complications. The first and last of these are the intangibles through which a lifelong commitment to healing allows physicians to excel. The critical decision-making resides with the physician.

It is our opinion that dermatologists are best prepared and equipped to plan, execute, and follow up on laser hair removal surgery. Patients who seek medically necessary laser hair removal may have symptoms more complex than simply unwanted hair and may require outcomes that extend beyond the surgical reduction of hair. Many of these procedures will be performed on facial skin where a broad range of ancillary dermatologic procedures may be brought to bear to create a satisfactory result and make a meaningful difference in patient satisfaction. Many will have underlying health conditions or may be taking medications that may preclude safe laser surgery.

Medical knowledge increases daily, new technologies and treatment modalities come and go, and the health care system evolves and grows ever more complex. In this setting it is clear that improved outcomes can only occur when care is properly coordinated and managed. Allowing electrologists to perform laser hair removal moves us in a very different direction. By fragmenting and subdividing health care it will diminish skill and create barriers to communication that can only degrade the quality of care that can be delivered.





September 29, 2011

Jennifer L. Filippone, Chief
Practitioner Licensing and Investigations Section
Department of Public Health
410 Capitol Avenue, MS#12MQA
P.O. Box 340308
Hartford, CT 06134

Re: Impact Statement from State and National Dermatology Associations Regarding Proposed Scope of Practice Expansion, Connecticut State Electrology Association

Dear Ms. Filippone:

Pursuant to Public Act 11-209 and on behalf of the Connecticut Society of Eye Physicians, and the American Academy of Ophthalmology, we are writing to voice our opposition to the Connecticut State Electrology Association's request to expand the scope of practice of licensed electrologists to include the removal of body and facial hair through the use of laser or light-based devices cleared by the U.S. Food & Drug Administration upon successful completion of a further course of study as required by the Connecticut Board of Examiners of Electrologists and approved by Department of Public Health.

Please contact William Malitsky, Principal, Halloran and Sage at Malitsky@halloran-sage.com or (860) 944-8297 if you have any questions about this statement.

Sincerely,

David K. Emmel, MD

President

Connecticut Society of Eye Physicians

Daniel J. Briceland, MD Secretary for State Affairs

James J. Grunda

American Academy of Ophthalmology

RECO SEP 3 O 2011

# Appendix E

# CONNECTICUT GENERAL STATUTES CHAPTER 388 ELECTROLOGISTS

## Section 20-267. Definitions. As used in this chapter:

- (1)"The practice of electrology" means the permanent removal of superfluous hair by electrical or other methods approved by the commissioner of public health;
- (2)"Board" means the Board of Examiners of Electrologists; and
- (3)"Department" means the department of public health.

Section 20-268. Board of examiners. There shall be in the department of public health a Board of Examiners of Electrologists, composed of five members, one of whom shall be a doctor of medicine licensed to practice medicine and surgery in the state and a diplomate of the American Board of Dermatology, two of whom shall be public members and two of whom shall be practicing electrologists who are residents of this state. The governor shall appoint the members of said board, subject to the provisions of section 4-9a. Said board shall meet at least once during each calendar quarter and at such other times as the chairman deems necessary. Special meetings shall be held on the request of a majority of the board after notice in accordance with the provisions of section 1-21. A majority of the members of the board shall constitute a quorum. Members shall not be compensated for their services. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from office. Minutes of all meetings shall be recorded by the board. No member shall participate in the affairs of the board during the pendency of any disciplinary proceedings by the board against such member. No professional member shall be an elected or appointed officer of a professional society of electrologists or have been such an officer during the year immediately preceding his appointment. Said board shall (1) hear and decide matters concerning suspension or revocation of licensure, (2) adjudicate complaints against practitioners and (3) impose sanctions where appropriate.

Section 20-269. Powers and duties of board. Assistance to be rendered by department of public health. The department of public health shall hold examinations at least twice each year at such times and places as the commissioner of public health determines. The commissioner of public health, with advice and assistance from the board, shall make regulations for the administration of this chapter and for the conduct of the business of electrology, which regulations may prescribe requirements concerning the layout, use and equipment of licensees' places of business, all in accordance with the public interest, health and safety. The board, with the consent of the commissioner of public health, shall prescribe the course of training for the practice thereof and shall adopt a schedule and minimum educational requirements. The board shall keep a record of the proceedings of said board, which shall be open to public inspection. The department shall provide the board with all necessary clerical and other assistance, keep its records and files, collect the fees due under this chapter and conduct any investigations and inspections required for the purposes hereof.

Section 20-270. Licenses; examinations; disciplinary action; grounds. No person shall engage in the practice of electrology, except as hereinafter provided, until he has obtained a license issued by the department. No person shall receive a license, except as hereinafter provided, until he has passed a written, oral and practical examination prescribed by the department with the advice and consent of the board. The examination shall be administered to applicants by the department under the supervision of the board. All applications to the department for examination shall be in writing signed by the applicant and upon blanks, furnished by the department, which shall set forth such facts concerning the applicant as the department may require. Application to the department shall be accompanied by a fee of one hundred fifty dollars. No person shall be eligible for examination under the provisions of this chapter unless the department finds, from evidence satisfactory to it, presented by the applicant, that he has met the educational and other requirements prescribed

license and his annual registration certificate. Such licensee shall not use any title, including the title "Doctor" or "registered nurse" or their synonyms or abbreviations, except "electrologist", and shall not use any adjective or qualification in addition to such title except that such licensee may use the title "certified professional electrologist" or its abbreviation "CPE" provided he has been awarded certification by the international board of electrologist certification of The American Electrologist Association.

<u>Section 20-277.</u> Scope of chapter. No provision of this chapter shall be construed to confer any authority to practice medicine or surgery; nor shall this chapter prohibit the practice of electrology by a person licensed to practice the healing arts or a person employed in a hospital or in the office of a licensed physician under his immediate direction; nor shall this chapter prohibit the use of nonelectrical cosmetic devices or the use of wax or other proprietary depilatories used for the temporary removal of superfluous hair from the surface of the skin.

Section 20-278. Prohibited acts. No person shall: (1) Buy, sell or fraudulently obtain or furnish any diploma, certificate, license, record or registration purporting to show that any person is qualified or authorized to practice electrology, or participate in any such act; (2) practice or attempt or offer to practice electrology under cover of any diploma, certificate, license, record or registration illegally or fraudulently obtained or signed, or issued unlawfully or under fraudulent representation or mistake of fact in a material regard; (3) practice or attempt or offer to practice electrology under a name other than his own or under a false or assumed name; (4) aid or abet practice by a person not lawfully licensed to practice within this state or by a person whose license to practice has been suspended or revoked; or (5) use in his advertising the word "electrologist" or any description of services involving permanent hair removal, without having obtained a license under the provisions of this chapter; and no person shall, during the time his license is revoked or suspended, practice or attempt or offer or advertise to practice electrology or be employed by, work or assist, in any way, any person licensed to practice electrology. Any person who violates any provision of this section shall be fined not more than one hundred dollars or imprisoned not more than thirty days or both.

#### Continuing Education for Electrologists

## Continuing Education for Electrologists

## 20-275b-1. Definitions

For the purposes of sections 20-275b-1 to 20-275b-7, inclusive, of the Regulations of Connecticut State Agencies:

- (1) "Active practice" means the treatment in Connecticut of one or more patients by a licensee during any given registration period;
- "Certificate of completion" means a document issued to a participant by a provider which certifies that the participant has successfully completed a continuing education activity;
- (3) "Contact hour" means a minimum of fifty minutes of continuing education activity, unless otherwise specified in these regulations;
- (4) "Department" means the Department of Public Health;
- (5) "Face-to-face instruction" means in-person, live instruction which a participant physically attends, either individually or as a part of a group of participants;
- (6) "Home study program" means continuing education activities, clearly related to maintaining skills necessary for the safe and competent practice of electrology that require the successful completion of a proficiency examination and are sponsored, endorsed or approved by the American Electrology Association or its affiliates;
- (7) "Licensee" means an electrologist licensed pursuant to section 20-270 of the Connecticut General Statutes;
- (8) "License renewal due date" means the last day of the month of the licensee's date of birth;
- "Participant" means a licensee who successfully completes a continuing education activity;
- (10) "Provider" means the individual educator or sponsoring organization conducting a continuing education activity; and
- (11) "Registration period" means the one-year period for which a license has been renewed in accordance with section 19a-88 of the Connecticut General Statutes and is current and valid.
  (Added effective July 25, 2002.)

#### 20-275b-2. Number of contact hours required

- (a) Each licensee applying for license renewal shall have completed a minimum of ten contact hours of qualifying continuing education during the preceding registration period, at least two of which shall be in infection control, blood borne diseases, universal precautions or sanitation and sterilization, or any combination thereof.
- (b) Continuing education contact hours completed in one registration period shall not carry over to a subsequent registration period.
- (c) Each licensee applying for license renewal shall sign a statement attesting that the licensee satisfies the continuing education requirements specified in section 20-275b-1 to section 20-275b-7, inclusive of the Regulations of Connecticut State Agencies. (Added effective July 25, 2002.)

# 20-275b-3. Basic requirements for qualifying continuing education activities

- (a) Qualifying continuing education activities are the following:
  - courses offered or approved by the American Electrology Association or its affiliates;
  - (2) hospital or medical school sponsored educational offerings, provided the coursework is related to health issues of practitioners;
  - (3) post-graduate coursework offered at electrology schools approved in accordance with section 20-269 of the General Statutes of Connecticut for the purposes of licensure, either audited or by credit;

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#### Hypertrichologist Licensure Requirements

#### Hypertrichologist Licensure Requirements

#### 20-269-3. Definitions

As used in sections 20-269-3 to 20-269-8, inclusive, of the Regulations of Connecticut State Agencies:

- (a) "Department" means the Department of Public Health.
- (b) "Board" means the Board of Examiners of Electrologists. (Effective October 30, 1987; Amended effective March 8, 2001; Amended effective July 25, 2002.)

#### 20-269-4. Pre-professional education

All applicants for licensure shall be high school graduates or hold a high school equivalency diploma issued by the appropriate state educational or federal armed services authority. (Effective October 30, 1987.)

#### 20-269-5. Professional education program approval

- (a) In order for a professional education program to be utilized by an applicant for licensure, it must meet the following requirements:
  - The curriculum shall consist of a minimum of six hundred hours of electrology instruction.
  - (2) The curriculum shall include the following:
    - At least two hundred hours of classroom instruction in basic sciences applicable to electrology, including but not limited to: bacteriology, sanitation and hygiene, biology, dermatology, trichology, theory of electricity, electrolysis and principles of infection control.
    - (B) At least four hundred hours of practical instruction in epilation techniques, utilizing electrolysis (direct current/DC) and thermolysis (alternating current/AC) modalities.
- (b) Programs shall be individually reviewed and approved by the Board with the consent of the Department. The program shall submit such materials as may be required to the Board and Department for the purpose of review and approval. (Effective October 30, 1987; Amended effective March 8, 2001; Amended effective July 25, 2002.)

#### 20-269-6. Professional education

- (a) All applicants for licensure shall have successfully completed a curriculum of electrology instruction approved by the Board with the consent of the Department in accordance with Section 20-269-5 of the Regulations of Connecticut State Agencies.
- (b) The electrology instruction shall be completed within a program which holds all licensure, approval, and accreditation required by Connecticut or such other state as the program is located within.

## (Effective October 30, 1987; Amended effective July 25, 2002.)

#### 20-269-7. Infection control standards

- (a) All licensed hypertrichologists shall maintain infection control standards during the practice of hypertrichology to include, but not be limited to the following:
  - Universal blood and body fluid precautions as recommended by the centers for disease control;
  - (2) A state of cleanliness in all treatment areas;
  - Cleaning and sterilization of reusable instruments;
  - (4) Handling and disposal of instruments, needles and contaminated items.
- (b) A supply of non-sterile disposable examination gloves shall be available for use in the treatment areas at all times.

Current with materials published in Connecticut Law Journal through 09/01/2009

## Continuing Education for Electrologists

continuing education contact hours. (Added effective July 25, 2002.)

#### 20-275b-5. Record retention by licensees

- (a) Each licensee shall obtain a certificate of completion from the provider of continuing education activities. Certificates of completion shall be retained by the licensee for a minimum of three years following the license renewal due date for which the activity satisfies license renewal requirements.
- (b) The department may inspect such licensee records as it deems necessary. Certificates of completion shall be submitted by the licensee to the department only upon the department's request. The licensee shall submit such records to the department within 45 days of the department's request.
- (c) A licensee who fails to comply with the continuing education requirements of sections 20-275b-1 to 20-275b-7, inclusive, of the Regulations of Connecticut State Agencies may be subject to disciplinary action, pursuant to section 20-271 of the Connecticut General Statutes.
  (Added effective July 25, 2002.)

# 20-275b-6. Exemptions from and waiver of the continuing education requirements

- (a) A waiver of the continuing education requirements may be extended to a licensee who is not engaged in active practice during a given registration period provided the licensee submits, prior to the expiration of the registration period, a notarized application on a form provided by the department. The application shall contain a statement that the licensee shall not engage in active practice until the licensee has shown proof of completion of the requirements specified in sections 20-275b-1 to 20-275b-7, inclusive, of the Regulations of Connecticut State Agencies.
- (b) The department may, in individual cases involving a medical disability or illness, grant waivers of the minimum continuing education requirements or extensions of time within which to fulfill the requirements. The application for waiver or time extension shall be accompanied by a verifying document signed by a licensed physician. Waivers of the minimum continuing education requirements or extensions of time may be granted by the department for a period not to exceed one (1) calendar year. If the medical disability or illness, upon which a waiver or time extension has been granted continues beyond the period of the waiver or extension, the licensee shall reapply for the waiver or extension.
- (c) A licensee whose license is due to expire within twelve months of the effective date of sections 20-275b-1 to 20-275b-7, inclusive, of the Regulations of Connecticut State Agencies, shall be exempt from continuing education requirements until such licensee's next registration period.
- (d) A licensee applying for license renewal for the first time is exempt from continuing education requirements.

  (Added effective July 25, 2002.)

# 20-275b-7. Requirements for return to active practice following waiver of the continuing education requirements

A licensee who has received a waiver, pursuant to subsection (a) of section 20-275b-6 of the Regulations of Connecticut State Agencies, shall submit to the department evidence of successful completion of four contact hours of continuing education prior to returning to active practice, which shall be applied to the registration period during which the licensee was exempt from such continuing education requirements.

(Added effective July 25, 2002.)

## Electrologist Licensure Requirements

#### 20-269-3. Definitions

As used in sections 20-269-3 to 20-269-8, inclusive, of the Regulations of Connecticut State Agencies:

(a) "Department" means the Department of Public Health.

"Board" means the Board of Examiners of Electrologists.
 (Effective October 30, 1987; Amended effective March 8, 2001; Amended effective July 25, 2002.)

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  - (1) The curriculum shall consist of a minimum of six hundred hours of electrology instruction.
  - (2) The curriculum shall include the following:
    - (A) At least two hundred hours of classroom instruction in basic sciences applicable to electrology, including but not limited to: bacteriology, sanitation and hygiene, biology, dermatology, trichology, theory of electricity, electrolysis and principles of infection control.
    - (B) At least four hundred hours of practical instruction in epilation techniques, utilizing electrolysis (direct current/DC) and thermolysis (alternating current/AC) modalities.
- (b) Programs shall be individually reviewed and approved by the Board with the consent of the Department. The program shall submit such materials as may be required to the Board and Department for the purpose of review and approval. (Effective October 30, 1987; Amended effective March 8, 2001; Amended effective July 25, 2002.)

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- (a) All applicants for licensure shall have successfully completed a curriculum of electrology instruction approved by the Board with the consent of the Department in accordance with Section 20-269-5 of the Regulations of Connecticut State Agencies.
- (b) The electrology instruction shall be completed within a program which holds all licensure, approval, and accreditation required by Connecticut or such other state as the program is located within.

(Effective October 30, 1987; Amended effective July 25, 2002.)

## 20-269-7. Infection control standards

- (a) All licensed hypertrichologists shall maintain infection control standards during the practice of hypertrichology to include, but not be limited to the following:
  - (1) Universal blood and body fluid precautions as recommended by the centers for disease control;
  - A state of cleanliness in all treatment areas;
  - Cleaning and sterilization of reusable instruments;
  - (4) Handling and disposal of instruments, needles and contaminated items.
- (b) A supply of non-sterile disposable examination gloves shall be available for use in the treatment areas at all times.
- (c) A sink with hot and cold running water shall be accessible to the treatment area. (Effective October 30, 1987; Amended effective March 8, 2001.)

#### 20-269-8. Approved electrical methods

The electrical methods approved by the Commissioner of Public Health for the permanent

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#### Public Health Code

## Department of Public Health

#### 20-269-8. Approved electrical methods

removal of superfluous hair are those utilizing only needle/probe electrode type epilation which includes electrolysis (Direct Current/DC), thermolysis (Alternating Current/AC), or the blend (a combination of both electrolysis and thermolysis).

(Added effective March 8, 2001.)

# Appendix F

## **Curriculum for Electrologist Performing Laser**

The course consists of thirty (30) hours of instruction, which may include 15 hours of home-study didactic training, in the user of laser and light-based hair removal or reduction devices, that may include the following topics:

- A. Biology of hair
- B. Laser and light-based hair removal physics, including:
  - 1. The theory of traditional light.
  - 2. The theory of coherent light.
  - 3. The electromagnetic spectrum
  - 4. The different types of laser and light-based hair removal devices.
  - 5. The history of laser and light-based device development
  - Understanding photonic principles and how a light-based device works.
  - 7. Hair removal laser and light-based device delivery systems.
- C. Safety and precautions including:
  - Federal and quasi-federal regulatory agencies and their roles in safety.
  - 2. Treatment room considerations
  - 3. Eye safety for the operator and the patient.
  - 4. Fire safety.
- D. Laser and light-based tissue interaction including:
  - 1. Grothus draper law
  - 2. Reflection, transmission, scatter and absorption
  - 3. The melanin and hemoglobin absorption curve at various hair removal device wavelengths.
  - 4. Depth of penetration and wavelength.
  - 5. Possible effects of absorption of light energy.
  - 6. Selective photo-thermolysis including:
    - a) Wavelength
    - b) Pulse duration
    - c) Energy fluence
    - d) Spot size.
    - e) Sanitation
    - f) Fitzpatrick skin typing
    - g) The patient intake form
    - h) Consultation
    - Proper documentation of patient case history and consent forms.
    - j) Pre-treatment patient preparation including test spot considerations and the Nikolski sign

- k) Treatment contra-indications including the recognition of disease conditions of the skin.
- 1) Hand-piece and spot size considerations.
- m) Fluence setting
- n) Stretch techniques
- o) Use of grid stamp
- p) Post-treatment procedures, including application of ice and after treatment care.
- E. Instructions to patients:
  - 1. Expected outcomes including erythema and edema
  - 2. Possible adverse outcomes
  - 3. Follow-up care
  - The concept of using needle-type epilators to complement laser or light-based hair removal or reduction devices;
- F. Hands-on experience with laser and light-based devices to include hair removal and reduction from all areas of the body.
- G. The instructors of each laser and light-based hair removal courses must have 2years minimum of post training experience verifiable documentation of this experience must be submitted to the Board with their application.

# Appendix G

#### **ASDSA Summation of Chart & Map**

- 14 States require onsite medical supervision for procedures delegated to electrologists, cosmetologists, or estheticians (AL, CT, FL, GA, KY, LA, MI, MS, MT, NH, NJ, NM, OK, UT)
- 11 State require initial physician examination and <u>offsite medical supervision</u> for procedures delegated to electrologists, cosmetologists or estheticians (AZ, AS, CO, IN, IA, KS, NC, OH, RI, SC, WI)
- 12 States do not allow electrologists, cosmetologists or estheticians to perform laser hair removal <u>under any circumstances</u> (CA, ID, IL, MD, MN, NE, ND, OR, SD, TN, VT, WA
- 9 States & District of Columbia do not specify laser hair removal within the law (AK, DE, DC, HI, ME, NV, MO, PA, WV, WY)

Allow electrologists, cosmetologists & estheticians to perform laser hair removal without any medical supervision: (NY, VA)

2 States where status is in conflict: (MA, TX)

Electrologists/cosmetologists could potentially perform laser hair removal without medical supervision either because not specified in law, specifically allowed in law, or in conflict in law in a maximum of 13 states and the District of Columbia.

# Appendix H

#### Feature:

## Complications from Laser Procedures Performed by Non-Physicians

- By Vic A. Narurkar, M.D.

Results of a study that quantifies and analyzes the problems that can occur when non-physicians perform laser procedures.

he last few years have witnessed an unparalleled growth in device-based aesthetic medicine using lasers, light sources and radiofrequency devices. Often, products are brought to market with limited clinical data and limited long-term studies, which are valuable to have because these studies typically offer insight into potential complications.

In addition, we've seen rapid proliferation of non-physician use of these devices. Adding to the problem is the great state-by-state variability of device regulation. Also, the definition of "physician" supervision ranges from direct on-site supervision to facilities with medical directors who are physically located in other offices.

These factors are contributing to the increase in complications dermatologists are seeing. To get a better sense of the magnitude of this problem, colleagues and I conducted a study at my private practice laser center.

## Study Background

The study, "Analysis of Complications from Lasers and Light Sources and Radiofrequency Devices by Non-Physicians," was presented at the American Society of Lasers in Medicine and Surgery annual meeting this year.

For this study, we reviewed 123 complications that resulted from treatment received from non-physicians. These patients presented as referrals over the course of 1 year. We reviewed the standard of care and corrective action that was given in my practice.

Three board-certified dermatologists with extensive expertise and advanced fellowship training in procedural dermatology (Drs. Tim Flynn, Ranella Hirsch and myself) analyzed the complications.

Analysis of the complications was based on the following criteria:

- types of complications
- cause of complication by indication
- complications by anatomic location
- nature of the device producing the complication
- nature of supervision of the non-physician provider.

# **Common Complications**

Hyperpigmentation represented the most common complication, followed by hypopigmentation and hypertrophic scar formation. Of the complications reviewed, 42% were permanent, as defined by persistence of the complication for more than 1 year after the incident, with hypertrophic and atrophic scars as the most common complication.

Hair reduction was the most commonly treated condition that resulted in complications (46%), followed by laser/light leg vein treatments (21%) and non-facial photorejuvenation (11%). Lower extremities were the most common location of complications (36%), followed by face (22%) and neck (12%). The most common cause of complications was the use of a device for an improper indication (35%), such as long- pulsed 1064 nm lasers for tattoo removal, pulsed light for melanocytic nevi and treatment of tanned skin with a variety of laser and light source devices.

Overutilization of a device for an indication (30%) for which an alternative therapy was superior represented the next most common cause of complications. Examples included the use of pulsed light for melasma and a long-pulsed 1064 nm laser for superficial lower extremity leg veins.

Devices involved in the highest number of complications were long-pulsed 1064 nm lasers and pulsed light without cooling. The least number of complications occurred with the flash-lamp pulsed-dye laser and Q-switched lasers.

Eighty two percent of all complications occurred in facilities that had no direct physician supervision. Of these, 57% were in facilities with a "medical director" who had limited training

in dermatologic procedures and laser/light-based therapy. Of all the complications, 78% occurred in non-traditional medical facilities, such as free-standing medical spas and laser

centers in shopping malls.

## Suggested Solutions

This study represents one of the few systemic studies undertaken to analyze complications by non-physicians using lasers, light sources and radiofrequency devices.1,2 This study found that the greatest risk factors for complications are:

- inappropriate use of or overutilization of devices
- lack of direct supervision by physicians with training in dermatology
- · inadequate cooling with devices.

Better training and education, better physician supervision, and standardization of the definition of physician supervision on a national level are necessary to help eliminate complications. In addition, better studies and long-term results of device usage will help reduce the overutilization and overpromotion of device-based aesthetic medicine.

Currently, a multi-center study is underway to analyze the short- and long-term complications by non-physicians in the practice of device-based medicine.

#### References:

1. Friedman PM, et al. "Nonphysician practice of dermatologic surgery: The Texas perspective." Dermatologic Surgery. 2004; 30:857-63.

2. Greve B, Raulin C. "Professional errors caused by lasers and intense pulsed light technology in dermatology and aesthetic medicine." Dermatologic Surgery. 2002;28:156-61.

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# Appendix I

# Medical spas are the new litigation hot spot, attorneys say.

by Tresa Baldas

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Byline: TRESA BALDAS

THE BOOMING medical spa industry is suffering some aches and pains. The diagnosis? Malpractice lawsuits. The prognosis? Not so good.

Plaintiffs and defense attorneys alike say medi-spas, where the beauty-conscious go to lose their unwanted facial hair, acne scars and fine lines, are a new litigation hot spot as patients increasingly sue over spa treatments gone wrong. Laser hair removal in particular is triggering lawsuits, lawyers note, warning that even more litigation is on the horizon as the number of medical spas has soared.

"Oh my gosh, [litigation] is going to be exploding in the next couple of years because of how frequent and often people are having these procedures done," said Thomas Boleky of Beutel Hurst Boleky, a personal injury firm in Chicago. "No one really regulates them. I think that's part of the problem."

According to the International SPA Association, which represents 3,200 spas globally, medical spas are the fastest growing segment of the spa industry and have quadrupled in numbers in recent years, from 471 in 2004 to 1,804 today. Unlike day spas, which specialize in services such as massages, facials and body wraps for relaxation, medical spas offer cosmetic procedures that often involve the use of medical devices, such as lasers.

While most states require that a doctor supervise such procedures, lawyers say it is not happening. Some states, including New York Florida and Illinois, are considering legislation that would more tightly regulate medical spas. In the meantime, medi-spa claims are showing up on dockets around the country.

Mr. Boleky himself has two medi-spa malpractice suits in the pipeline and in recent years has settled a handful of similar cases, including that of a Chicago woman who in 2007 won a \$100,000 settlement from the now-bankrupt Pure Med Spa over scarring on her neck caused by a laser treatment to remove age spots.

In Arizona, a woman on Aug. 11 sued Timeless Laser & Skin in Maricopa County Superior Court alleging she was "severely burned and scarred" during laser hair removal. Also in Arizona state court, a man in April sued Neos Medspa over scarring, "extreme pain" and burning he allegedly suffered from laser hair removal on his back and shoulders. In North Carolina, a woman in January won a

\$500,000 judgment against a medical spa over a serious blood infection she allegedly developed from a procedure to reduce fat in her stomach.

The plaintiffs bar is "gaining steam" in targeting the medical spa industry, said Jill Goldsmith, managing partner of the Phoenix office of Bowman and Brooke, which is defending a handful of medi-spa lawsuits. She warned that worse days lie ahead.

"I believe we're seeing the beginning of this industry being targeted," Ms. Goldsmith said. "Both mom-and-pops and chain companies have sprung up around the country in the past few years, creating a new billion-dollar industry and litigation hot spot."

But medical spas can take immediate action to guard against litigation, said Ms. Goldsmith, who is alerting her clients to be extra cautious in fully disclosing risks to their patients and obtaining and documenting informed consent.

Ms. Goldsmith said she believes that people wrongly assume nothing will go wrong at a medi-spa.

"They have perhaps unrealistic expectations and assume that going to a medical spa is risk-free, and it's not," she said. "No procedure is risk-free."

To "stay ahead of the litigation," medical spas need to go the extra mile in informing patients about possible risks, Ms. Goldsmith said. For example, when a potential patient comes in for a procedure, the spa should consider showing a video or pictures of the procedure and explain what could go wrong.

Lynne McNees, president of the International SPA Association, said in a statement that members of her group "adhere to a standards-and-practices agreement, as well as a code of conduct that lists the rights of spagoers."

Patients, Ms. McNees suggested, should bear some responsibility when seeking treatments from a medical spa.

"It is important to be an advocate for yourself and do your homework before visiting any spa," she said.

# Appendix J





# Adverse Events Associated With Nonablative Cutaneous Laser, Radiofrequency, and Light-Based Devices

Elizabeth Dawson, MD, Andrea Willey, MD, and Ken Lee, MD

Medical and esthetic indications and demand for nonablative laser and light-based treatments are increasing. Although these are generally safe procedures, laser practitioners should be aware of potential complications that may be associated with therapy. An adverse event may be defined as any undesirable effect, even if expected, that occurs with laser treatment. These adverse events can be related to patient factors, professional errors, common side effects, and more serious complications. A variety of providers, including nondermatologists, perform laser treatments and must be aware of therapeutic outcomes as well as potential complications after laser surgery. Clinical indications for nonablative laser treatments, common side effects, and more serious adverse events will be reviewed in addition to treatment and prevention of these potential complications.

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KEYWORDS laser complication, adverse event, side effect, outcome

The use of laser, light, and radiofrequency energy devices  $oldsymbol{1}$  is rapidly evolving for both medical and esthetic indications. Although these treatments generally are safe and well-tolerated, the complexity of procedures and potential for adverse events should not be underestimated. A basic understanding of laser physics is essential for the safe and effective operation of these devices. The theory of selective photothermolysis revolutionized the safety and efficacy of nonablative laser therapy by allowing thermal injury to be spatially confined to the target chromophore.1 In addition, the development of tissue-cooling methods have greatly extended the therapeutic profile of modern laser practice.2 More recent advances in optical technology have expanded the principles of selective photothermolysis to take advantage of less selective tissue heating.3 Complications associated with these new devices may not be as predictable or readily detectable by observing immediate tissue reactions. Despite optimizing treatment parameters for a specific clinical indication and patient factors, a provider may nevertheless en-

counter adverse events due to device failure and should be aware of this potential source of error.

An adverse event constitutes any undesirable effect, even if expected, that occurs with laser treatment. Even in the hands of physicians with high levels of training and expertise, complications occur during and after laser treatment and should be anticipated and managed properly. This article will outline clinical indications for nonablative laser treatments and the mechanisms of tissue injury that result in both common, expected side effects and serious adverse events. Finally, we will discuss ways to minimize and treat these potential complications.

#### **Patient Factors**

A thorough discussion with a patient is necessary preoperatively to provide detailed information regarding the planned treatment, potential benefits and side effects, treatment alternatives, and cost. Adequate patient consultation is necessary to promote realistic expectations, ascertain the patients' acceptance of potential side effects, and discuss the possibility of treatment failure or recurrence of the condition being treated. A provider should ideally offer the patient photographic examples of potential treatment complications. Emphasis on postoperative care, including ice packs, photoprotection, and clinical follow-up are essential to minimize

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unwanted outcomes. Proper documentation of the patient consultation, consenting process, and preoperative photographs are recommended.

Patient factors can markedly affect the outcome of laser surgery and should be evaluated before initiation of therapy. These include the indication for treatment, location of the lesion, Fitzpatrick skin type, presence of a suntan, and planned outdoor activities. Patients with darker skin types are more likely to have postoperative dyspigmentation and warrant conservative treatment with lower fluence, longer wavelengths, and adequate tissue cooling. Performing test spots 2 weeks before initiating treatment and observing for adverse side effects can be valuable in these patients to reduce the risk of complications. The patient's medical history, including infections (ie, herpes simplex virus), connective tissue disease (a marker of photosensitivity), or vascular abnormalities may be contraindications to laser surgery. Other risk factors include a history of keloids or abnormal scarring, postinflammatory hyperpigmentation, and a family history of pigmentary abnormalities. Review of the patient's medication list and allergies is essential to avoid or minimize side effects such as bleeding, increased bruising, delayed healing, scarring, pigment alteration, or localized chrysiasis. 4,5 Potentially problematic medications include retinoids, minocycline, gold, amiodarone, warfarin, acetylsalicylic acid, niacin, nonsteroidal anti-inflammatory drugs, and vitamin E. Finally, a laser practitioner should establish whether the patient has had any previous cosmetic surgeries or procedures that may interfere with the laser treatment or alter tissue response.

#### Professional Errors

Professional errors may result from inadequate training, improper laser operation, insufficient documentation, limited patient information, incorrect diagnosis or treatment indication, and failure to perform test treatments. Strategies to obviate some of these preventable adverse events are succinctly reviewed by Greve and coworkers<sup>6</sup> and are beyond the scope of this article. Many complications can be avoided or minimized by carefully monitoring the tissue reaction to the laser treatment. An experienced laser surgeon can usually recognize an immediate adverse response such as tissue whitening or graying which indicates thermal injury and requires prompt discontinuation of treatment and review of device parameters and function.

Importantly, many laser practitioners are not dermatologists and may erroneously treat a pigmented lesion that is in fact a melanoma, pigmented basal cell carcinoma, or atypical nevus. A laser practitioner should be aware of the potential for misdiagnosis of malignant skin lesions and the necessity of dermatologic evaluation of pigmented lesions. Finally, strict laser safety is important to protect the patient, provider, and potential bystanders during laser operation. Proper administration of laser surgery requires education and practical training to minimize the risk of ocular and cutaneous injury, fire, and electrical hazards.

## Complications by Indication

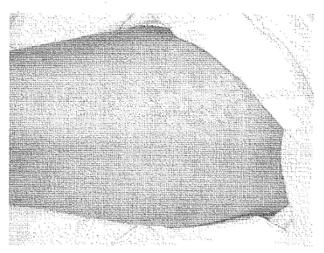
#### Vascular Lesions

Acquired and congenital vascular lesions such as facial telangiectasia, port wine stains, infantile hemangiomas, and leg veins are frequent indications for laser treatment. Lasers and light sources commonly used to treat vascular lesions include the flashlamp-pumped pulsed-dye laser (PDL; 585-600 nm), long-pulsed Potassium Titanyl Phosphate (KTP; 532 nm), Alexandrite (755 nm), Neodymium Yttrium Aluminum Garnet (Nd: YAG; 1064 nm), and broad-spectrum intense pulsed light (IPL) sources. IPL devices target both vascular and pigmented lesions and will be discussed separately. Vascular specific lasers target intravascular oxyhemoglobin, transferring thermal energy to the surrounding blood vessel wall. Parameters such as wavelength, pulse duration, and fluence are optimized to decrease unintentional tissue injury. If the pulse duration of the laser exceeds the thermal relaxation time of the target chromophore, thermal diffusion and tissue damage may occur. Historically, treatment of vascular lesions with the continuous-wave argon laser, argon-pumped tunable dye laser, copper vapor, and copper bromide lasers were frequently associated with adverse effects such as scarring and permanent dyspigmentation. These complications are now significantly reduced with newer pulsed-dye lasers that operate with extended pulse durations and incorporated cryogen spray cooling to minimize collateral tissue injury. Because of its superior safety and efficacy profile, the PDL is the most commonly used laser to treat vascular lesions.

Purpuric parameters often are needed to effectively treat vascular lesions such as hemangiomas and port wine stains. A purpuric response is a frequent side effect of treatment and occurs most often with short pulse durations that cause vaporization and rupture of superficial vessels and extravasation of red blood cells. The use of extended pulse durations may prevent significant purpura, however these subpurpuric parameters often require multiple treatments, pulse-stacking, and multiple passes to achieve the targeted clinical endpoint. Common side effects include transient erythema and edema. Edema typically resolves within a few days of laser treatment but can be significant, particularly with pulsestacking and treatment with more than 250 pulses.7 Posttreatment edema may be considerable in periocular areas. Management of purpura is usually supportive with application of ice packs, topical corticosteroids, and petrolatum if ulceration occurs. Postoperative edema and erythema is treated with similar supportive measures as well as head elevation; more severe cases may benefit from a short course of oral corticosteroids.

In addition, treatment of vascular lesions with the PDL will often produce a reticulated pattern due to the Gaussian distribution of energy within a laser pulse. Overlapping pulses by 18% can minimize this "honeycomb" appearance, however even with diligent pulse overlapping, both reticulate pattern erythema and dyspigmentation can occur (Fig. 1).8

Because of its close approximation to the peak absorption of hemoglobin, the KTP laser (532 nm) is well suited for the

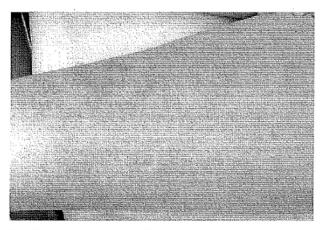


**Figure 1** Postoperative hypopigmentation after treatment with a 595-nm pulsed-dye laser. (Color version of figure is available online.)

treatment of superficial telangiectasia using short millisecond pulses. Transient linear crusting followed by temporary dyspigmentation is a common side effect after KTP laser treatment and typically resolves within a week of therapy. Application of petrolatum to erosions is useful to expedite wound healing.

Transient or permanent dyspigmentation can follow treatment of vascular lesions with many laser and light devices because melanin coabsorption occurs throughout the visible and near-infrared spectrum (Fig. 2). Postinflammatory hyperpigmentation is typically reversible although it may last for months, particularly in patients with darker skin types. For this reason, treating a spot and observing the patients' tissue response four to six weeks later can be helpful to gauge the potential for dyspigmentation. Patients should be advised to avoid excessive sun exposure postoperatively and apply sunscreen diligently.

Ulceration, scarring, and textural changes are rare with proper patient selection and appropriate treatment parameters. Observing the immediate tissue reaction for vessel co-



**Figure 2** Hyperpigmentation after treatment with a 595-nm pulsed-dye laser. (Color version of figure is available online.)



**Figure 3** Dermal depressions on the nasal alar crease after treatment of telangiectasia with a long-pulsed 532-nm KTP laser. (Color version of figure is available online.)

agulation and epidermal changes is essential to monitor tissue response. Striking erythema or graying of the epidermis is a sign of excessive thermal damage. Adequate cooling is essential to minimize damage to surrounding tissue and the potential for scar formation. In addition, dermal depressions have been observed several weeks to months after treatment of larger facial vessels or refractory alar telangiectasia (Fig. 3). <sup>10</sup> These lesions may resolve spontaneously and can benefit from gentle massage. In more severe cases, nonablative laser treatment or cosmetic fillers may improve textural appearance.

Because of their deeper optical penetration, long-pulsed red and near-infrared lasers such as the Alexandrite (755 nm) and Nd: YAG (1064 nm) are commonly used to treat larger facial vessels and leg veins. Although venous ectasias on the lower extremities are most effectively treated with sclerotherapy, vascular lasers are useful for patients who are not candidates for this procedure. Because absorption of hemoglobin is greatly reduced at longer wavelengths, high fluences are required to achieve vessel coagulation and cooling is therefore essential. With the use of long pulse durations, both pre and parallel cooling are applied. In the event of cooling failure significant ulceration can occur. The use of overly aggressive treatment parameters and pulse stacking should be strictly avoided.

More complex vascular lesions such as hemangiomas, thick port wine stains, and venous malformations may benefit from treatment with infrared lasers such as the Nd: YAG (1064 nm). Because of great variability in the threshold for thermal injury within these complex vascular malformations, laser treatment should be limited to experts who are familiar with the complicated morphology of these lesions. <sup>10,11</sup> Combination laser devices that can deliver multiple wavelengths are being developed and will likely improve the efficacy and safety profile for treatment of these complex vascular lesions. <sup>12</sup>

## Benign Pigmented Lesions

Solar lentigines, ephelides, and flat seborrheic keratoses are benign pigmented lesions commonly treated with Q-

switched lasers. The importance of correct diagnosis of pigmented lesions before laser treatment cannot be overemphasized. Evaluation by a dermatologist before a laser procedure is recommended to verify that the pigmented lesion of concern is not malignant. The lasers commonly used to treat benign pigmented lesions operate in the Q-switched nanosecond range and include the Ruby (694 nm), frequency-double Nd: YAG (532 nm), and Alexandrite (755 nm). By virtue of being Q-switched, thermal damage is largely confined to pigment within melanosomes, minimizing collateral tissue injury.

Expected side effects after treatment with pigment-specific lasers include immediate, superficial tissue whitening followed by mild erythema and edema. Vesiculation and crusting may be observed within 1 to 2 days; healing is usually complete by 10 to 14 days. More severe blistering can occur with use of high fluences or in the presence of dense pigmentation. Application of petrolatum ointment is necessary for optimal wound healing and can minimize scar formation in the case of significant blistering.

Transient postinflammatory hyperpigmentation is common after an erythematous tissue response and typically improves over time. Treatment options include topical bleaching creams or chemical peels for more severe facial hyperpigmentation. Persistent postoperative hypopigmentation can occur with the use of high fluences and may improve over time although it is often refractory to treatment.

Scarring can occur with the use of aggressive treatment parameters and poor patient selection. When treating pigmented lesions, it is advisable to initially use the lowest effective fluence and titrate upwards based on immediate tissue response. Stacking pulses and multiple passes over a target should be avoided with Q-switched lasers.

In general, the risk of side effects with pigment-specific lasers increases with the relative absorption of melanin for a specific wavelength. Because of greater melanin absorption, blistering and dyspigmentation can be more prominent with the 532-nm frequency-doubled Nd: YAG and the 694-nm Ruby laser. These lasers should be used cautiously in deeply pigmented lesions and avoided in patients with darker skin types or suntanned skin. Conversely, the 1064-nm Nd: YAG has a lower incidence of side effects and can be safely used in more heavily pigmented skin.

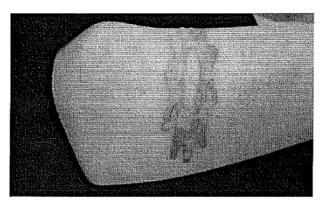
# **Tattoo Pigment**

Professional, amateur, cosmetic, and traumatic tattoos also are effectively treated with Q-switched pigment-specific lasers. Generally therapy is well tolerated, with similar side effects as those discussed with treatment of benign pigmented lesions. Patients typically need multiple laser therapy sessions depending on the quality of the tattoo (professional typically requiring more than amateur), age of the tattoo, and pigment composition. It is essential to avoid treating a patient with suntanned skin because a pigment-specific laser cannot discern constitutional pigment from exogenous tattoo pigment.

Red and near-infrared Q-switched lasers (Alexandrite 755 nm, Ruby 694 nm, Nd: YAG 532 and 1064 nm) are effective for lightening black pigment. The Alexandrite (755 nm) and Ruby (694 nm) lasers are well-suited for targeting green pigment while green laser light (Nd: YAG 532 nm) is the best choice to treat red, orange, and yellow tattoo inks. Incomplete removal with residual pigmentation is not uncommon with tattoo treatment. Particular tattoo pigments are more difficult to treat with laser devices and include those with turquoise blue, purple, and yellow inks. Tattoos previously treated with chemical peels or salabrasion are potentially more resistant to laser removal secondary to fibrosis and scarring. Furthermore, in some tattoos pigment overlying the original tattoo ink may obscure the original tattoo colors and present a challenge for treatment because of the density of pigment in the skin. Lastly, IPL devices and other millisecond lasers lead to scarring and should not be used to for tattoo removal (Fig. 4).

It is important to do a test spot when treating tattoos to verify that the fluence being used is not disproportionate to the amount of tattoo pigment. Using excessive fluence can result in edema, blistering, bleeding, crusting, and possibly scarring. For this reason, treatment should start with the lowest fluence and largest spot size and be titrated according to treatment response.14 In the event of postoperative crusting and erosions, petrolatum ointment is essential to promote wound healing and minimize scarring. Any blisters the occur after treatment should be left intact. After laser treatment, photoprotection is essential to prevent postinflammatory hyperpigmentation and minimize the potential for suntanning skin before subsequent laser treatment. When treating large extremity tattoos, it is important to be aware of the number of pulses delivered. Excessive pulse quantity per treatment session has resulted in closed-compartment syndrome of the upper extremity requiring decompressive volar fasciectomy.15

Dyspigmentation is a common adverse event and should be expected after multiple treatments with pigment-specific lasers. Hypopigmentation is more likely to be permanent because repeated laser treatments will decrease constitutional pigment as well as residual tattoo pigment. Postinflammatory



**Figure 4** Treatment of a tattoo with a long-pulsed hair removal laser resulted in hypertrophic scarring. (Color version of figure is available online.)

hyperpigmentation is common, particularly in dark skinned individuals, but is usually transient. Use of an appropriate ratio of fluence to pigment density can minimize dyspigmentation.

Complications unique to laser treatment of tattoos include oxidation, allergic, and ignition reactions. Oxidation of tattoo ink results in irreversible, immediate pigment darkening of tattoos that contain iron oxides or white ink. The paradoxical darkening is secondary to a chemical reaction reducing ferric oxide or titanium dioxide that is present in red or white pigment, respectively. Performing a test spot is imperative to evaluate the candidacy of the tattoo for laser treatment and advise the patient accordingly. Cosmetic tattoos or multipigmented tattoos that contain white ink should not be treated. Treatment with the Nd: YAG laser may lighten the oxidized pigment, however these darkened tattoos are typically refractory to laser therapy. Alternatives for tattoo removal include surgical excision, dermabrasion, and ablative laser treatment.

Various types of hypersensitivity reactions to tattoo ink have been described. Laser fragmentation of pigment-containing cells liberates tattoo pigment extracellularly where it has the potential for increased antigenicity. Clinically a patient may manifest erythema, dermatitis, urticaria, or a localized granulomatous reaction. Topical or intralesional steroids can be used for symptomatic relief. Laser tattoo removal should not be attempted in patients with a history of hypersensitivity, redness, or swelling associated with tattoo ink due to risk of exacerbating an allergic reaction and potential for systemic hypersensitivity and anaphylaxis. If the patient has a history of systemic allergic reaction to tattoo pigment, treatment options include mechanical removal of the tattoo with surgical excision or laser ablation. In the presence of hypersensitity, oral corticosteroids are given before and after ablative methods of removal and resuscitative equipment should be available if needed. Evaluation by an allergist before treatment may be recommended in some cases.

Ignition of gunpowder is a rare but potential complication with firecracker or traumatic tattoos. Laser ignition may result in fire, explosion, and scarring. <sup>16</sup> There may be a potential cancer risk from chemicals released as ignition byproducts. <sup>17</sup>

## **Photoepilation**

Laser reduction of unwanted hair is a popular, generally well-tolerated procedure. Lasers within the red and infrared range, including the long-pulsed Ruby (694 nm), Alexandrite (755 nm), Diode (810 nm), Nd: YAG (1064 nm), in addition to broad-spectrum intense-pulsed light sources are used for photoepilation. Long pulsed lasers target melanin within hair follicles causing thermal damage to the follicle and temporary miniaturization of the hair shaft. 18

When a patient presents for laser hair removal, it is important to discuss realistic expectations after therapy. Response to treatment depends on the hair color, shaft diameter, skin type, and hormonal factors. The ideal candidate for photoepilation is an individual with fair skin and dark, coarse hair. The efficacy of laser hair removal is greater with the use of

higher fluences. 18 However, the inappropriate use of excessive fluences is associated with an increased risk of complications. Thus, optimal results of photoepilation depend on both practitioner skill and knowledge of device operation.

Common side effects with photoepilation include mild pain with treatment, erythema, and perifollicular edema. Severe pain can be an indication of excessive fluences or inadequate cooling. Dyspigmentation, blistering, and even scarring may also occur and are more common in patients with darker skin types, a suntan, or when lasers in the red spectrum are used. The Nd:YAG is the preferred laser for treatment of dark skinned individuals because of its longer wavelength, deeper penetration, and reduced melanin absorption. However, permanent hair removal is less common with longer wavelengths and repeated treatments are usually needed.

Burns resulting from cooling failure associated with both operator error and device failure have been described. Arcuate-shaped burns may result from angling of the hand piece during treatment of curved surfaces leading to misalignment of the cryogen spray relative to the laser spot. <sup>19</sup> It is important to keep the laser hand piece perpendicular to the skin, particularly when treating curved areas such as the face and legs. Additionally, annular burns may occur with the use of insufficient cryogen spurt duration for a given spot size. A minimum spurt duration of 40 milliseconds is recommended for a spot size of 15 mm, and 50 milliseconds for an 18-mm spot size. <sup>19,20</sup> Heating of accumulated debris on the guidepost may also lead to ring-shaped burns.

Less common and poorly understood complications of photoepilation include reticulate erythema, paradoxical hypertrichosis, and urticarial-like plaques. Reticulate erythema has been described after hair reduction treatment with the diode laser. This uncommon side effect is poorly understood but may result from interaction between the laser energy and the underlying vasculature. Patients with a history of pernio or collagen vascular disease may be at higher risk of this complication.21 Paradoxical hypertrichosis has been described after photoepilation with both lasers and IPL devices and may be more common than previously believed. 22,23 Urticaria-like plaques have occurred after laser hair reduction and may be pruritic and persist for days to weeks. The etiology of these lesions is not understood but symptoms may improve with the use of topical corticosteroids and oral antihistamines.

# Nonablative Resurfacing

Compared with ablative techniques, nonablative resurfacing is less invasive with shorter recovery time and fewer adverse effects. Several devices are currently used to achieve improvements in skin texture and laxity, including visible, near infrared and mid-infrared lasers, radiofrequency energy sources, intense pulsed light devices, and combinations of these modalities. These devices are thought to stimulate dermal collagen remodeling and rely on tissue cooling to minimize epidermal damage.

Proper technique is essential with these devices because of the absence of a visible epidermal reaction on which to gauge treatment response. Patient feedback on pain sensation is important during the procedure to guide treatment parameters and should be observed closely. Aggressive anesthesia is a risk factor for adverse events because patient pain perception may be blunted and excessive thermal damage may occur.

Common side effects after nonablative skin resurfacing include moderate erythema and edema. These usually resolve within 1 to 2 days of treatment. Complications primarily result from overheating tissue with excessive energies or inadequate cooling. Adverse events include severe pain, dyspigmentation secondary to epidermal injury, blistering, and scarring. Treatment with appropriate parameters as well as pre, parallel, and posttherapy tissue cooling can minimize these complications. Management of these adverse outcomes is largely supportive.

Radiofrequency (RF) tissue tightening is a unique nonsurgical treatment of skin laxity and tissue contour. Controlled heat modification of collagen stimulates a wound healing response with immediate contraction of collagen fibrils and delayed formation of new collagen. Late side effects such as cutaneous depressions can occur weeks or months postoperatively and result from overheating of adipose tissue and fibrous septae with monopolar RF devices. Caution must be used when treating over bony prominences or thin skin such as the forehead and temples; drawing skin away from bony prominences during treatment is recommended to minimize contour irregularities. Treating with lower fluences and multiple passes is advised to decrease the risk of adverse events.24 Mild dermal depressions often resolve spontaneously over time. More severe contour irregularities and scarring may improve with surgical subscision, autologous fat transfer, or cosmetic fillers.24

Near and midinfrared lasers target water surrounding dermal collagen, stimulating dermal remodeling to improve the textural appearance of acne scarring and fine lines from photoaging. Epidermal cooling is crucial to decrease blistering and the risk of scarring. Excessive "bulk heating" of the dermis without visible clinical endpoints may lead to catastrophic burns. Patients should be counseled regarding reasonable expectations for treatment outcome. Maximal dermal remodeling and textural changes usually peak 6 months after treatment. These changes may be subtle and in some patients clinically inapparent.

Fractional resurfacing is a promising new laser used to treat fine lines, dyspigmentation, and some forms of scarring. The fractional resurfacing device creates small columns of spatially confined thermal injury called microscopic treatment zones (MTZ) that specifically spare surrounding tissue. Uninjured epidermis and dermis that surrounds MTZs promote healing while intact stratum corneum overlying the MTZ serves as a biologic dressing. Common side effects during treatment include mild pain, erythema, and edema. In addition to topical anesthesia, use of air cooling and lower fluences can minimize intraoperative discomfort. Posttreatment erythema and edema are typically mild and usually resolve over a few to several days but may last longer. <sup>25</sup> Al-

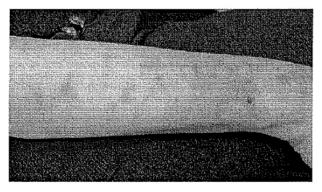
though anesthesia is necessary for treatment, caution is warranted to monitor the dose and duration of topical lidocaine application to avoid toxicity from systemic absorption.

Complications with fractional resurfacing can occur with high treatment densities that result in confluent areas of thermal damage without intervening zones of healthy tissue to promote wound healing. Immediate tissue whitening results from excessive treatment densities and may result in permanent hypopigmentation. Similar to other lasers, more severe adverse outcomes can occur with the use of excessive passes or high fluences.

## Intense Pulsed Light

The intense pulsed light system emits noncoherent broadband light in the range of 515 to 1200 nm. Indications for IPL treatment are numerous and include pigmented and vascular lesions, photoaging, and photoepilation. Complications associated with earlier IPL devices are much improved with the use of dichroic filters and incorporation of cooling within the handpiece. The broad range of wavelengths used in IPL devices increases the potential for side effects associated with absorption of epidermal pigment. Thus, even with the use of new devices, proper application of cooling devices is essential.

Common side effects after treatment with IPL include mild postoperative erythema and edema. More serious superficial burns and scarring can occur with aggressive treatment parameters. These can be minimized by the use of appropriate treatment settings, cooling methods, and proper patient selection. Patients should also be advised regarding photoprotection with sun avoidance and sunscreen to minimize postinflammatory hyperpigmentation after an erythematous treatment response. Because of the potential for competition between different chromophores with IPL systems, this device should be used cautiously in darkly pigmented and suntanned skin. Complications arising from IPL devices are similar to lasers, however with a larger spot size, the inability to visualize immediate tissue effects with contact cooling tips, and the broad spectrum of light exposure, there is potential for serious thermal injury if used improperly (Fig. 5).24 Be-



**Figure 5** Scarring and dyspigmentation after the use of aggressive treatment parameters with an intense pulsed-light source. (Color version of figure is available online.)

cause IPL devices do not operate in the nanosecond pulse duration range they should not be used for tattoo removal as this results in significant thermal tissue injury and scarring.

Care should be taken to maintain slight overlap between pulses to ensure confluent treatment of the target area and avoid "skip" (untreated) areas. These "skip" areas may leave a footprint of dyspigmentation in contrast to neighboring treated areas (Fig. 5). Transient neurologic sequelae are potential anecdotal complications after IPL treatment of skin overlying bony prominences, particularly in elderly patients with thin, atrophic skin. Temporary neuropraxia may be minimized by decreasing the energy delivered by the IPL system in these high-risk areas. In addition, the use of conservative treatment parameters and diligent cooling is prudent when treating the neck and genital skin, which is typically thinner and more darkly pigmented.

## Summary

Current lasers, RF devices, and light-based sources are widely used by many practitioners with varying degrees of laser training and experience. Most Q-switched and pulsed lasers adhere to the concept of selective photothermolysis in which thermal injury is largely spatially confined to specific tissue chromophores and thermal damage to surrounding tissue is minimized. Recent advances in optical technology include devices that do not strictly adhere to principles of selective photothermolysis, targeting chromophores that are not spatially confined such as water surrounding collagen, as well as noncoherent light and energy sources. With all laser and light-based treatments, adequate cooling and epidermal protection are crucial to minimize and prevent adverse events. Although these modalities are generally safe, incorrect or overaggressive use of any laser or light device has the potential for irreversible complications such as scarring and permanent dyspigmentation. Operator education and experience are essential to master the skills to deliver appropriate treatment, prevent adverse outcomes, and manage postoperative complications.

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# Appendix K



CASE SERIES

Ocular complications of laser-assisted eyebrow epilation

S Shulman and I Bichler

#### Abstract

Purpose To report a series of patients with ocular complications associated with laser-assisted eyebrow hair removal. Patients and methods Case reports of three patients with eye pain and photophobia following laser epilation of the eyebrow region. The eye examination included visual acuity, slitlamp examination, tonometry and fundoscopy. The follow-up period was 3 months. Results Each patient had conjunctival hyperaemia in one or both eyes and anterior chamber pigmentary cells. One patient presented with posterior synechiae, which did not respond to treatment. Conclusions Laser epilation of the eyebrows may result in anterior uveitis as well as irreversible damage to the iris. Eye (2009) 23, 982-983; doi:10.1038/eye.2008.436;

Keywords: laser epilation; eyebrow; iritic damage; iatrogenic

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#### Introduction

Laser-assisted epilation is currently the most efficient long-term method for body and facial hair removal. Various laser systems are available for this use, such as ruby laser (694 nm), alexandrite (755 nm), diode (800 nm), and neodymium-YAG (1064 nm). I Periocular (eyebrow) laser hair removal is rarely associated with complications. We present three cases of ocular complications caused by diode laser-assisted removal of eyebrow hair.

#### Case reports

#### Case 1

A 27-year-old healthy lady with mild myopia had undergone laser epilation of both eyebrows.

She had shut her eyes during the treatment. 2 days later, she complained of severe pain and photophobia in both eyes. Eye examination revealed multiple pigmentary cells in both anterior chambers and posterior synechiae in both eyes (Figure 1). She received topical steroid and topical cyclopentolate, with no improvement. A subconjunctival injection of atropine (0.01 mg) and adrenaline (0.01 mg) to the left eye had no effect. The eye condition had not altered at the 1-week and 3-month follow-up examination: her anterior chambers were clear but the dilated pupil and posterior synechiae in the left eye persisted, (Figure 2) as did the severe photophobia.

#### Case 2

A 35-year-old healthy lady with no previous eye problems, presented with the complaints of pain and redness in her right eye 1 week after undergoing eyebrow laser epilation. Protective shields had been used during most of the treatment, but she was instructed to cover her eyes with two fingers because of difficulties in treating the lower eyebrow region. On examination, her uncorrected visual acuity was 6/6 in both eyes. The right eye had moderate conjunctival injection, multiple pigmentary cells in the anterior chamber, and pigment on the anterior capsule of the lens. Both the pupils were round and reactive, and the left eye was quiet. Treatment with topical steroids and cycloplegic drops led to resolution of the signs and symptoms within 2 weeks. The 3-month follow-up examination was normal apart from pigment on the anterior lens capsule of the right eye.

#### Case 3

A 24-year-old healthy lady with no previous eye problems, presented with complaints of pain,

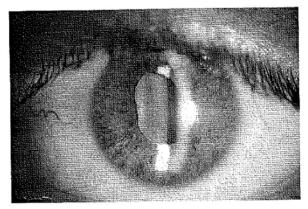


Figure 1 Posterior synechiae in the left eye of Case 1.

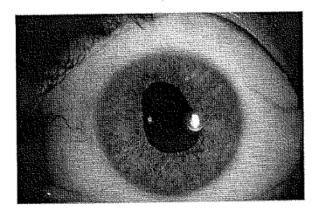


Figure 2 The posterior synechiae in the left eye of Case 1 is still present at the 3-month follow-up examination.

photophobia, and redness in her left eye 1 day after undergoing eyebrow laser epilation. She complained that she experienced severe photophobia and glare as soon as the laser treatment was over. Her uncorrected visual acuity was 6/6 in both eyes. There was moderate conjunctival injection and multiple pigmentary cells in the anterior chamber of the left eye. The left pupil was dilated to 4 mm and partly reactive to light. Treatment consisted of topical steroids. The uveitis cleared within 1 week but the pupil remained dilated; it became round and reactive at the 6-week follow-up and remained so at the 3-month follow-up.

#### Comment

Laser epilation, based on selective thermolysis, is an increasingly popular method of long-term hair removal. The chromophore melanin of the hair follicle at the dermis level absorbs the delivered energy, rather than the more superficial epidermal melanin, which would result in depigmentation of the skin. The instruments used for dermatologic purposes are therefore planned to penetrate to a depth of 3-4 mm. The probe is supposed to be firmly placed on the treated skin to reach this depth, but this might be difficult to achieve on the inferior border of the eyebrow due to the structure of the orbital bones. The tendency to close the eyes during the procedure results in the eyes moving upwards under the closed eyelids (Bell's phenomenon), causing the pigmented iris to reach the laser penetration range and leading to a variety of clinical presentations, such as iritic atrophy, anterior uveitis and posterior synechiae.2,3

Our MEDLINE search yielded several published case reports on this subject. Halkiadanis et al2 described a 30-year-old lady who presented with iritic atrophy and posterior synechiae after eyebrow laser epilation. Her condition was unchanged 6 months after the procedure. Herbold et al3 reported a more severe case associated with iritic atrophy and cataract that eventually reduced visual acuity. The patients in the above cited cases had removed their protective goggles to facilitate hair removal from the lower part of the eyebrow. Shikh et al4 described a patient suffering from uveitis and visual field defect after photoepilation of the upper eyelid despite using protective shields.

We wish to raise the ophthalmologists' level of awareness of this form of cosmetic treatment as an iatrogenic cause of ocular damage. Individuals contemplating laser-assisted eyebrow hair removal must be advised of the potential risks to their eyes.

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# Appendix L

#### CASE REPORT

# Iritis and pupillary distortion after periorbital cosmetic alexandrite laser

Chih-Chung Lin · Po-Chen Tseng · Chun-Chen Chen · Lin-Chung Woung · Shiow-Wen Liou

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#### Abstract

Background To describe a case of ocular complications associated with laser-assisted periorbital cosmetic treatment and to recommend consideration of the ocular damage caused by dermatological laser therapy, including pupillary distortion and anterior uveitis.

Methods Case report.

Results A 29-year-old Caucasian woman underwent cosmetic alexandrite laser therapy in the left upper eyelid area without protective eye shields. She complained of an irregular oval pupil, photophobia, and blurred vision in her left eye. Initially, her best-corrected visual acuity (BCVA) was 30/25 (OD) and 30/25 (OS). Slit-lamp biomicroscopy revealed a distorted left pupil with 3+ cell activity in the anterior chamber, but normal intraocular pressure. She was treated with topical corticosteroids. However, marked anterior chamber activity, pigment dispersion over the iris surface, and deteriorating BCVA of 10/25 (OS) had developed at the two-week follow-up. The ocular inflammation subsided gradually and her BCVA returned to normal after intensive steroid treatment. At the six-month follow-up, an ocular examination showed poor pupillary motility and persistent pigment over the iris surface. The patient still suffered from glare in dim light and experienced problems with dark adaptation.

Conclusions Alexandrite laser treatment of the upper eyelid region may penetrate the eyelid, causing anterior uveitis and irreversible damage to the iris. We recommended appropriate eye protection during this therapeutic procedure.

Keywords Alexandrite laser · Iritis · Uveitis · Pupillary distortion

#### Introduction

Laser-assisted cosmetic applications are becoming popular, including in hair removal and the treatment of pigmented lesions. Various laser systems are available for these purposes, such as the ruby (694 nm), alexandrite (755 nm), diode (800 nm), and neodymium-YAG (1064 nm) [1]. We present a case of ocular complications after the use of alexandrite laser for the photo-depigmentation of periorbital freckles.

#### Materials and methods

A case report and literature review.

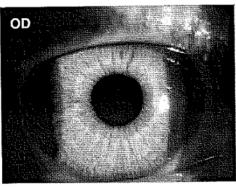
#### Results

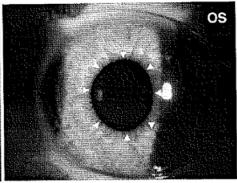
A 29-year-old Caucasian woman underwent cosmetic alexandrite laser therapy in the left upper eyelid area without protective eye shields or metal contact lenses. Although she closed her eyelids, she experienced a sharp ocular pain during the procedure. The energy fluence was 28 J/cm<sup>2</sup> with a pulse duration of 20 ms and a beam diameter of 12 mm. She complained of an irregular oval

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Fig. 1 A distorted pupil in the left eye, with an oval shape and a sluggish response to light, was initially noted (arrowhead)





pupil, photophobia, and blurred vision in her left eye immediately after treatment (Fig. 1). Her best-corrected visual acuity (BCVA) was initially 30/25 (OD) and 30/25 (OS). Slit-lamp biomicroscopy revealed a distorted left pupil with 3+ cell activity in the anterior chamber, but normal intraocular pressure (IOP).

Acute anterior uveitis was diagnosed, and treatment with topical corticosteroids (1% prednisolone acetate QID) and cycloplegics was commenced. However, a marked anterior chamber inflammatory reaction and keratoprecipitates, increased IOP to 34 mmHg, pigment dispersion over the iris surface, and a deteriorating BCVA of 10/25 (OS) had developed at the two-week follow-up. We administered the IOP-lowering agent Trusopt TID and intensive steroid treatment with triamcinolone acetonide 40 mg subtenon injection, and loteprednol etabonate QID. The ocular inflammation subsided gradually, and the IOP returned to within normal limits. A 30-degree automatic visual field examination was performed, which revealed no visual field defect. The crystalline lens remained clear, and there was no obvious damage or scarring to the retina. At the 6-month follow-up, this patient was receiving no treatment to the affected eye, and an ocular examination showed normal BCVA and IOP. The left pupil was still irregular and more dilated than the right pupil, but responded to light (Fig. 2). However, poor pupillary motility and persistent pigment over the iris surface were

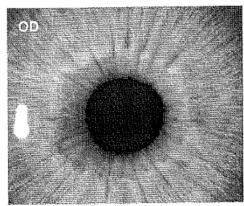
noted. The patient still complained of glare in dim light, and had difficulty with dark adaptation.

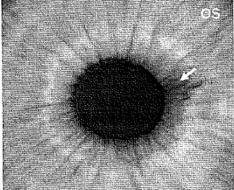
#### Discussion

The alexandrite is a long-pulsed infrared laser with a wavelength of 755 nm. Its principal dermatological applications include hair removal, tattoo treatment, and pigmented lesion removal [2]. The mechanism of dermatological laser treatments is based on the concept of selective photothermolysis [3]. The theory is that melanin-containing structures absorb the delivered energy, resulting in the depigmentation or photoepilation of the skin. Generally, the depth of laser penetration increases as the wavelength increases, and the optimal depth is 3–4 mm [3].

The lasers used for cosmetic therapy can potently damage the eyes. The retina and iris contain the highest concentrations of melanin in the body, and can be harmed by lasers when they are used within the periocular area. Previously published reports have demonstrated the adverse effects of dermatological laser treatments, including anterior uveitis, pupillary distortion, posterior synechiae, iris atrophy, nuclear cataract, visual field defect, macular hole, and retinal scarring [4–10]. Carrim et al. [4] described a woman suffering from iris damage and acute pigment dispersion

Fig. 2 At the 6-month followup, the left pupil was still irregular (oval) and more dilated than the right pupil, and its response to light and the pigment dispersion over the temporal side of the iris surface were obvious (arrow)





in her left eye following photoepilation of her eyebrows with an alexandrite laser. A marked superior iris transillumination defect was apparent after the initial injury. Lin et al. [5] reported a woman who sustained a traumatic macular hole in her right eye caused by an alexandrite laser applied to remove her freckles. Blurred central vision with a fresh-red shadow was noted immediately after laser exposure. Herbold et al. [6], Hammes et al. [7], and Halkiadakis et al. [8] also presented patients who experienced iritic atrophy and posterior synechiae after periorbital laser treatment, and an even more severe case associated with cataract formation.

In the case reported here, protective eye shields were not provided, and the patient's eyelids were too thin to shield the eye from the laser's energy. Bell's phenomenon of upgaze upon eyelid closure caused the pigmented iris to enter the laser penetration range and absorb the energy delivered. Melanin is an excellent absorber of green, yellow, red, and infrared wavelengths [1-3]. Caucasian people have less melanin in the stroma of the iris than other ethnic groups, which makes their eyes appear blue, and the blue iris surface has a less dense anterior border layer and more prominent trabeculae than those of the brown iris, which has a dense matted anterior border. Therefore, it is easier for the laser energy to penetrate the posterior structure of the blue iris, resulting in ocular injury in the posterior segment of blue-green eyes. The colors black, green, and blue also absorb the wavelength of the alexandrite laser relatively well [2, 3]. Consequently, the green-blue-colored iris in this patient had a strong tendency to absorb the delivered energy, resulting in pupillary damage.

Our patient was not provided with protective goggles, but only applied some gel over the periocular area. The absorption of the laser energy by the iris caused hyperthermia, and led to temporal atrophy of the iris muscle and subsequent damage. Increased IOP was detected a few days after the initial presentation, which might be attributable to topical steroid use or secondary open-angle glaucoma caused when the pigment dispersion obstructed the aqueous outflow from the anterior chamber. At the 6-month follow-up, the visual acuity of the left eye had returned to 20/20 and her IOP was normal. However, the left pupil retained an oval shape and poor motility. The patient still suffered from glare and difficulty in dark adaptation. We believe that these symptoms were related to the damage to the iris and

pupil. The long-term ocular complications from the laser damage in this patient have yet to be determined.

In conclusion, alexandrite laser treatment in the upper eyelid region may penetrate the eyelids, resulting in anterior uveitis and irreversible damage to the iris. Although these ocular complications usually occur in white populations, ophthalmologists in Asia should still be alert to the potential ocular injury in patients undergoing periorbital cosmetic laser therapy. We cannot emphasize too strongly the importance of the appropriate eye protection, such as eye goggles or metal contact lenses, supplied by the consulting ophthalmologist before this cosmetic laser treatment is performed. When approached by patients complaining of ocular pain after periocular cosmetic laser treatment, we should examine their eyes carefully to identify any damage to both the anterior and posterior segments.

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# Appendix M

use surgical instruments without restraint. The surgeon can see the scleral ports directly, making the insertion of instruments easier. The optical features, such as field of viewing retina (127 degrees) and image magnification (×0.384) are the same as with MiniQuad. Neither a small pupil nor filling the eye with gas has disturbed the high resolution of the entire retina.

A limitation with the ClariVIT is that it cannot provide a highly magnified image. We recommend, therefore, the use of ClariVIT in combination with a regular prismatic lens, magnifying prismatic lens,<sup>3</sup> and other techniques.

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## Diode-laser-induced Cataract and Iris Atrophy as a Complication of Eyelid Hair Removal

Harilaos S. Brilakis, MD, and Edward J. Holland, MD

PURPOSE: To caution about ocular risks of dermatologic diode laser, including cataract formation and iris atrophy. DESIGN: Observational case report.

METHODS: A 63-year-old woman underwent diode epilation in the upper eyelid area without protective eye shields and experienced a sharp ocular pain during treatment of her left eye. She later presented with decreased vision in that eye and sensitivity to light.

RESULTS: Iris atrophy and a nuclear cataract were seen on examination. In the absence of any such observations at previous eye examinations and of any contributory ocular history, these findings were attributed to the diode laser treatment.

CONCLUSION: Diode laser epilation in the upper eyelid region could entail risks for intraocular structures, including cataractogenesis and iris atrophy. (Am J Ophthalmol 2004;137:762–763. © 2004 by Elsevier Inc. All rights reserved.)

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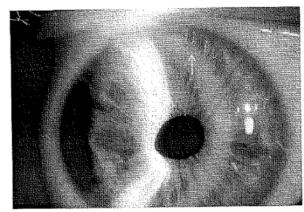


FIGURE 1. Anterior segment photograph of the patient's left eye; the arrow points at the area of iris atrophy superiorly. Nuclear sclerotic changes of the crystalline lens were also present.

ASER EPILATION HAS SEEN AN INCREASING POPULARITY as a means to achieve long-lasting hair removal in the field of cosmetic dermatology. Several laser types have been used for epilation, including the yttrium-aluminum-garnet (YAG), ruby, alexandrite, and diode lasers. Whereas precautions are clearly stated against periocular use with all those laser devices, in practice laser epilation is occasionally performed at the eyelid region, at times without protective ocular shields.

We report the case of a 61-year-old Caucasian woman who underwent epilation of both upper eyelids, approximately 2 to 5 mm inferior to the eyebrow line. The Lightsheer diode laser (Coherent Medical, Santa Clara, California, USA) was used. The patient reported a past ocular history significant only for a small refractive error and a normal eye examination with 20/20 corrected vision in each eye 6 months before her epilation. During the treatment, she did experience a short-lasting pain in her left eye. Over the course of the next few days, she noticed sensitivity to light, and, over the course of the next few weeks, a decrease in vision.

On presentation, 6 weeks after diode treatment, her bestcorrected vision was 20/20 in the right eye, 20/30+ in the left eye. External examination was unremarkable. On slit-lamp biomicroscopy, the cornea and conjunctiva were intact in each eye; iris atrophy was observed superiorly in the left eye, as shown in Figure 1. The lens demonstrated nuclear-sclerosis changes in that eye. Examination of the iris and the lens were normal in the fellow eye. Intraocular pressure was measured at 14 in each eye. Fundus examination was unremarkable.

Laser epilation has seen an increasing popularity as a means to achieve long-lasting hair removal in the field of cosmetic dermatology and has now become the treatment of choice. Several laser types have been used for epilation, including the YAG, ruby, alexandrite, and diode lasers. According to the laser hair-removal principle of selective thermolysis, it is the chromophore melanin of the hair follicle at the dermis level that absorbs the delivered energy, rather

than the hemoglobin or the more superficial epidermal melanin, which would result in depigmentation. Depth of penetration to the hair follicle is desired, as well as optimal absorption by melanin in the hair follicle, bulb, and shaft; a wavelength between 600 and 1,100 nm allows for those properties. In addition to wavelength, adequate fluence, a pulse length moderately above the thermal relaxation time of the pigmented anagen hair, and appropriate cooling systems allow for selective energy delivery to the melanin of the hair unit.<sup>2–4</sup>

The eyelid skin's limited thickness should alert against the possibility of energy delivery deep enough to reach the ocular structures. The normal Bell's phenomenon of upgaze upon eyelid closure may increase the risk of injury, by aligning the anterior segment of the eye with the upper eyelid area being treated. We are unaware of previous reports of a diode-epilation-induced cataract; a computerized MEDLINE search on intraocular side effects of laser epilation yielded one case in the German literature of diode laser energy absorption by the iris pigment epithelium, with subsequent uveitis and pupillary distortion.<sup>5</sup>

Awareness should be raised in the dermatology as well as the ophthalmology community of the potential complications of laser energy intraocular penetration. Periocular use of the diode and other hair-removal laser systems should be avoided and the patients advised of potential risks. Ocular shields should be used if the patients still opt for treatment.

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# Uveal Effusion Following Laser In Situ Keratomileusis (LASIK) for Hypermetropia

Thomas K. H. Butler, FRCOphth, Gerard Sutton, FRANZCO, FRACS, Con Moshegov, FRANZCO, FRACS, and David L. McKay, FRANZCO PURPOSE: To describe the first reported cases of uveal effusion syndrome following laser in situ keratomileusis (LASIK).

DESIGN: Interventional case reports.

METHODS: A 50-year-old woman developed bilateral submacular choroidal folds with subtle fluid elevation of the macula on the first day following uneventful LASIK for hypermetropia. A 48-year-old man developed right, prominent, 360-degree, peripheral choroidal effusions and submacular choroidal and retinal folds several months following LASIK for hypermetropia.

RESULTS: Case 1 was treated with systemic diclofenac and case 2 with systemic prednisolone. Both cases showed gradual improvement in vision over several weeks, returning to best-corrected visual acuity of 6/6.

CONCLUSIONS: Uveal effusion syndrome is a previously unreported complication that may occur following LASIK for hypermetropia. (Am J Ophthalmol 2004; 137:763–765. © 2004 by Elsevier Inc. All rights reserved.)

VEAL EFFUSION, CHARACTERIZED BY SEROUS CILIOchoroidal and retinal detachment has been reported following various ophthalmic procedures including cataract surgery, panretinal photocoagulation, and scleral buckling, as well as in a primary idiopathic form. We describe two cases, which represent the first reports of this complication related to laser in situ keratomileusis (LASIK).

• CASE 1: A 50-year-old female underwent routine, bilateral LASIK. She had no relevant general medical or ocular history, and took no medication. Preoperative refraction was +2.25 diopters (DS) on the right, and +2.50/-0.50 × 35 on the left with 6/6 vision on each side. Intraocular pressure (IOP) was 16 mm Hg bilaterally, with healthy fundi. Axial lengths were 21.4 mm, and scleral thickness was normal. The uneventful procedures were performed with the Summit Krumeich-Barraquer Microkeratome (SKBM, Alcon Laboratories, Inc., Texas, U.S.A.) keratome.

The next day, she complained of bilateral blurred vision, worse on the right. Vision was 6/60 unaided (6/12 with pinhole) on the right, and 6/18 (6/6 with pinhole) on the left. She had well-positioned LASIK flaps, clear interfaces with no striae, and quiet anterior chambers; IOP was 10 mm Hg bilaterally. There were bilateral macular choroidal folds with subtle subretinal fluid, worse on the right (Figure 1). Retinae were flat peripherally.

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# Appendix N

# Iris atrophy and posterior synechiae as a complication of eyebrow laser epilation

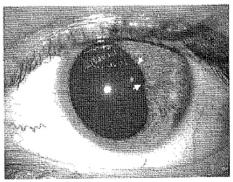
Ioannis Halkiadakis, MD,<sup>a</sup> Sotiris Skouriotis, MD,<sup>a</sup> Christina Stefanaki, MD,<sup>b</sup> Eleni Patsea, MD,<sup>a</sup> Dimitrios Papakonstatudinou, MD,<sup>c</sup> Apostolos Amariotakis, MD,<sup>a</sup> and Gerasimos T. Georgopoulos, MD<sup>c</sup> Athens, Greece

aser-assisted hair removal is the most efficient long-term hair removal currently available. Various laser systems have been used for that purpose including ruby laser (694 nm), alexandrite laser (755 nm), diode laser (800 nm), and neodymium:yttrium-aluminium-garnet laser (1064 nm). Most of the time, more than one treatment session is needed. Reported complications are not serious and include crusting and vesiculation of treatment site, hypopigmentation, and hyperpigmentation. We describe a case of iris atrophy and posterior synechiae as a complication of eyelid hair removal.

#### CASE REPORT

A 30-year-old Caucasian woman presented to our clinic for evaluation for refractive operation. On examination her best-corrected visual acuity was 20/20 ou with moderate myopia and astigmatism. Slit-lamp examination produced unremarkable findings and fundus revealed normal results. Two months after the evaluation the patient received diode laser epilation of both upper eyebrows. The patient reported that she wore safety glasses during the procedure. One week after the epilation the patient presented to the emergency department with increased sensitivity to light in her left eye. Her visual acuities were 20/20 on both eyes.

On examination, marked iris atrophy and posterior synechiae were observed on her left eye (Fig 1). Less marked iris atrophy was observed on her right eye. There were neither cells nor flare in the anterior



**Fig 1.** Anterior segment photograph of patient's left eye after pupillary dilation demonstrating pupillary distortion caused by iris atrophy and defects of sphincter pupillae. *Arrow*, Posterior synechiae between iris and lens.

chamber. Examination of the lens was normal in both eyes. Intraocular pressure was 14 mm Hg ou. Fundus examination produced unremarkable findings. At the last examination 6 months later the patient still had photophobia in her left eye but no cataract was present in either eye.

#### DISCUSSION

Laser hair removal is accomplished through follicular unit destruction. The ability to remove hair without damaging the surrounding skin is based on selective photothermolysis: the theory that selective thermal damage of a pigmented target will result when sufficient fluence at a wavelength preferentially absorbed by that target is delivered. Generally, the depth of laser penetration increases with increased wavelength and is 3 to 4 mm for diode lasers. <sup>2,3</sup>

All lasers used for hair removal are potent eye hazards. The retina contains the highest concentration of melanin in the body and can be damaged by lasers when used within the bony orbit. There are several recent reports of eye complications after diode laser epilation.<sup>3-5</sup> Brilakis and Holland<sup>4</sup> described a 61-year-old woman with iris atrophy and visually significant cataract in her left eye induced by

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diode epilation of both upper eyebrows. Similarly, Herbold et al3 reported a 27-year-old woman with superior segmental defects of the sphincter pupillae of irises, displacement of the pupil, and focal anterior subcapsular lens opacities in both eyes. The patient reported that the safety glasses were removed because of difficulties in the epilation of hairs from the inferior border of the eyebrows. This fact together with Bell's phenomenon on closing the eyes allowed the absorption of laser energy by superior area of the iris. The patient noticed photophobia immediately after the procedure because the pupil was not reactive to light. Our patient did not have any lens injury, but iris injury causing photophobia, which persisted. This case is consistent with the typical time line for photophobia induced by iris atrophy. Some degree of inflammation of the iris immediately after the injury may have exacerbated our patient's symptoms but no iritis was present at the time of the examination.

Generally, laser hair removal around the eyes is not recommended.6 However, if laser epilation is to be performed, the dermatologist should ensure the correct placement of protective eyewear and should not rely on any other assisting personnel. Because the spot size of the laser system depends on the device and certain devices do not provide small enough spot sizes (<8 mm) to fit on the inferior

eyebrow, then the simple protective eyewear seems inappropriate for treating that anatomic location and a safer alternative would be the internal contact lens. If the "unibrow" is to be treated, then one way to avoid any eye injury is to stretch the skin between the brows upward onto the frontal bone, away from the eyes.2 If these precautions cannot be adequately held, then another traditional epilation method may be chosen.

Our observation and previous reports strongly suggest that lasers should not be used to remove the lower eyebrow because of the danger of inducing iris and lens injury.

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