

BOARD OPINION
RELATING TO LASER SURGERY

LEGAL AUTHORITY

Pursuant to KRS 311.602, the following Board opinion is issued to assist Board licensees in determining what actions would constitute unacceptable conduct under the provisions of KRS 311.595. The Board has decided to publish this opinion because it addresses issues of significant public and medical interest.

This opinion is not a statute or administrative regulation and it does not have the force of law.

ACCEPTABLE AND PREVAILING MEDICAL PRACTICES OF LASER SURGERY

I. INTRODUCTION

This opinion is issued in order to (1) encourage and promote the delivery of quality care by physicians delivering dermatologic laser care and (2) assist those outside our profession in understanding the complexities and scope of care.

The Board has determined that the following principles constitute the standards of acceptable and prevailing medical practice relating to the delivery of dermatologic laser care. In making this determination, the Board has considered the relevant statutes (which are cited where appropriate), practice standards relating to physicians' conduct and interactions with other health care professionals and basic practice standards.

II. DEFINITION

In this opinion, "lasers" (*Light Amplification by the Stimulated Emission of Radiation*) are sources of high-intensity, monochromatic light that can be advantageously employed in the treatment of a variety of diseases depending on the wavelength, the pulse characteristics, and the true irradiance of the laser being used and the nature of the clinical condition being treated. In addition, it is the Board's opinion that high-intensity incoherent and multichromatic pulsed light may be used with the same principles of selective targeting by proper choice of wavelength spectrum, pulse characterization, and fluence.

III. TYPES OF LASERS

In this opinion, the Board recognizes that laser surgery is a rapidly changing field in which new types of lasers, as well as the conditions amenable to treatment, are continually being introduced. The conditions listed below have been treated using the particular laser or group of lasers by different physicians with varying results.

A. Visible light lasers emitting continuous wave radiation and recognized by the skin

Lasers in this group include the continuous-wave and quasi-continuous-wave visible light lasers, which are the argon laser (488-514 nm); the continuous-wave dye laser, usually tuned between 585 and 600 nm; the copper vapor laser (511-578 nm); the continuous-wave potassium titanyl phosphate (KTP) lasers (532 nm); and the krypton

laser (521, 530 and 568 nm). All these lasers produce continuous or shuttered visible laser light. In general, it is the Board's opinion that the acceptable and prevailing medical practice is to use laser wavelengths from 532 to 595 nm predominantly in the treatment of vascular disorders and wavelengths from 488 to as high as 532 in the treatment of benign pigmented disorders. With all these continuous and quasi-continuous devices the ability to spatially confine thermal damage is difficult. Thus, unlike treatment with the pulsed dye and pulsed KTP laser, the final outcome is highly dependent on the skill of the laser operator. Computer-driven mechanical scanning devices have been developed to ensure more uniformity of treatment and to help contain the thermal injury spatially, thus reducing the risk of using these continuous and quasi-continuous lasers.

1. Argon laser and continuous-wave argon-pumped dye laser

The argon laser produces visible light at 6 wavelengths between 488 and 514 nm. In the continuous wave argon-pumped tunable dye laser an argon laser is coupled to a dye cavity to produce visible laser light of differing wavelengths depending on the type of dye placed in the laser cavity. The dyes that are used absorb strongly in various portions of the physical spectrum to produce colored light. By choosing the appropriate dye, it is possible to produce a desired wavelength or color of laser light. Dye lasers employed for the treatment of cutaneous vascular disorders use rhodamine dye having a peak emission at or near 577 nm. Fine tuning can be achieved by using a prism to increase or decrease the emitted wavelength by up to 20 nm.

2. Copper vapor lasers

Copper vapor lasers produce either yellow light at 578 nm or green light at 511 nm by heating elemental copper or copper salts in the optical cavity. The energy is released as a chain of low-energy, short, 20 to 40 ns pulses at a frequency of 10 to 15 kHz. This chain can be electronically shuttered to produce bursts of pulses of 0.075 to 0.3 seconds in duration.

3. Krypton laser

The krypton laser is a gas-medium laser that emits either yellow light at a wavelength of 568 nm to treat vascular lesions or green light at wavelengths of 521 and 530 nm to treat pigmented lesions.

• **Conditions amenable to continuous and quasi-continuous wave laser treatment:**

Vascular lesions:

- Angiokeratomas
- Angiolymphoid hyperplasia
- Superficial (capillary) hemangiomas
- Cherry angiomas
- Blue rubber bleb nevi (perform adequate biopsy before to laser treatment)
- Essential telangiectasia

- Red nose caused by telangiectasia seen in the posttraumatic red nose syndrome
- Facial and truncal telangiectases of a variety of causes including rosacea, solar-induced chronic dermatitis, radiation dermatitis, CREST syndrome, and Osler-Weber-Rendu syndrome
- Spider angiomas
- Lymphangiomas
- Kaposi's sarcoma (perform adequate biopsy before to laser treatment)
- Port-wine stains (particularly those which are deeply colored, cobblestoned and nodular in surface texture when the nonspecific thermal effects are desired)
- Pyogenic granulomas
- Venous lakes

Benign pigmented disorders:

- Café-au-lait macules
- Lentigines
- Early, relatively flat, seborrheic keratoses

Miscellaneous conditions:

- Adenoma sebaceum
- Fibrous papule of the nose (perform adequate biopsy before to laser treatment)
- Glomus tumors (perform adequate biopsy before to laser treatment)

B. Visible light pulsed vascular lasers

Flashlamp-pumped pulsed dye laser(s) pulses of yellow light at a wavelength of 585, 590, 595, or 600 nm. The characteristics of these laser systems induce selective thermal damage confined to cutaneous vessels, making them, in the Board's opinion, most effective in the treatment of port wine stains and benign cutaneous ectasias. In the Board's opinion, the shorter pulse duration and the shorter wavelength pulse dye laser may be more effective for smaller, more superficial vessels, while the newer longer pulse duration (1.5 msec), longer wavelength (595) pulsed dye laser may be more effective for deeper, larger vessels, and for leg veins.

1. Pulsed KTP lasers

A group of pulsed KTP (532 nm) and Nd:YAG (1064 nm) lasers has been developed with pulse durations in the 1 to 100 ms range, which induce spatially confined thermal injury to cutaneous vessels. In the Board's opinion, they are effective in the treatment of benign vascular ectasias and some port-wine stains.

2. Visible light, pulsed nonlaser sources

By using wavelength filters, a broad band of light from either 515, 550, 570, or 590 nm to approximately 1000 nm is produced with a high intensity flashlamp. Depending on the filter chosen, treatment spectra are 515 to 1000nm, 550 to 1000 nm, etc. The pulse width may be adjusted from 1 to 10 msec and the interval between pulses, as well as the fluence, may be selected. Because of the mix of wavelengths used, a more nonspecific response may be seen with competing tissue chromophores. However, in the Board's opinion, the longer pulse widths and longer wavelengths may be useful in treating larger vessels.

- **Conditions amenable to pulsed lasers and pulsed light sources:**

Vascular lesions:

- Angiokeratomas
- Angiolymphoid hyperplasia
- Blue rubber bleb nevi (perform adequate biopsy before laser treatment)
- Superficial (capillary) hemangiomas
- Telangiectatic superficial leg veins
- Cherry angiomas
- Essential telangiectases
- Posttraumatic red nose syndrome
- Port-wine stains (large nodular mature port-wine stains usually require repeated treatments)
- Spider angiomas
- Facial and truncal telangiectases of a variety of causes including rosacea, solar-induced chronic dermatitis, radiation dermatitis, CREST syndrome, and Osler-Weber-Rendu syndrome
- Venous lakes

Miscellaneous conditions:

- Warts
- Hypertrophic scars

C. Short-pulsed pigment lasers

A group of short-pulsed lasers is effective for treatment of a variety of benign pigmented disorders. All have pulse durations less than 1 μ s, the thermal relaxation time of 1- μ m diameter melanosomes. Their effect is through combined photoacoustic and photothermal effects.

1. Q-switched ruby laser

The Q-switched ruby laser produces very short pulses (25 ns) of high-intensity red light at a wavelength of 694 nm. Because red light penetrates through the dermis, in the Board's opinion, the Q-switched ruby laser is effective for the treatment of both epidermal and dermal benign pigmented disorders, as well as blue, black, and green tattoos.

2. Q-switched and millisecond pulsed neodymium yttrium aluminum garnet (Nd:YAG) laser

The Q-switched Nd:YAG laser produces 5 to 10 ns high-intensity pulses at 1064 nm in the near infrared spectrum. The laser can be frequency doubled by means of a KTP doubling crystal to produce green light at 532 nm. Light at 1064 nm penetrates several millimeters into the depths of the dermis; therefore, even deep dermal pigmented disorders, including black and blue tattoos, can be treated. The 532 nm light penetrates only into the upper dermis and, in the Board's opinion, is not effective for deep melanocytic processes but is well suited for treatment of superficial pigmented lesions, such as lentigines and red, orange, and purple tattoos. In combination with a carbon-based topically applied solution, it is an acceptable and prevailing medical practice that Q-switched Nd:YAG lasers may be used to temporarily remove hair and to remove superficial layers of skin for skin rejuvenation.

3. Q-switched alexandrite laser

The Q-switched alexandrite laser produces either 50 or 100 ns high-intensity pulses at 755 nm in the red portion of the spectrum. Like the Q-switched ruby laser, in the Board's opinion, alexandrite laser light is effective for treatment of epidermal and dermal pigmented processes and black, blue, and green tattoos.

4. Pulsed dye laser (510 nm)

This pulsed dye laser produces short pulses (300 ns) of green (510 nm) light and, in the Board's opinion, it is the acceptable and prevailing medical practice that it be used for the treatment of epidermal pigmented disorders and red, orange, and purple tattoos. The wavelength is not long enough to penetrate sufficiently to affect deeper dermally pigmented disorders, such as nevus of Ota.

• **Conditions amenable to treatment with the short pulsed lasers:**

Benign pigmented lesions (epidermal):

- Lentigines
- Cafe-au-lait macules
- Ephelides
- Epidermal melasma
- Nevus spilus (perform adequate biopsy before laser treatment)
- Becker's nevus
- Lower labial macule
- Peutz-Jeghers spots

Benign pigmented lesions (dermal):

- Dermal melasma may lighten with treatment, but almost invariably recurs with sun exposure.
- Nevus of Ota
- Nevus of Ito
- Blue nevi (flat) (perform adequate biopsy before laser treatment)

- Mongolian spot
- Postinflammatory hyperpigmentation
- Hyperpigmented scars

Tattoo

D. Long pulsed long wavelength lasers

A group of longer pulsed, non-Q-switched, relatively long wavelength lasers has recently been developed in an effort to damage larger cutaneous targets selectively.

1. Long pulsed ruby laser

Long pulsed ruby lasers produce up to 60 J/cm^2 in 0.3 to 3.0 ms pulses at 694 nm.

2. Long pulsed alexandrite laser

Long pulsed alexandrite lasers more than 20 J/cm^2 and pulse durations of 3-20 ms at 755 nm.

3. Flashlamp pumped pulsed light sources

This device emits up to 60 J/cm^2 over a broad band in 2 to 20 ms pulses at wavelengths above 590, 615, 645, or 690 nm to an upper limit of approximately 1000 nm.

4. Pulsed diode lasers

Pulsed diode lasers produce up to 40 J/cm^2 in 5-30 ms pulses at 810 nm.

5. Pulsed Nd:YAG lasers

Long pulsed Nd:YAG lasers produce up to 150 J/cm^2 in 50 ms pulses at 1064 nm.

- **Conditions amenable to treatment with long pulsed long wavelength lasers:**

- Excessive facial or body hair
- Veins (0.4-1.5 mm diameter)

E. Continuous-wave carbon dioxide (CO₂) laser

The CO₂ laser produces invisible, mid-infrared light at a wavelength of 10,600 nm. In the Board's opinion, it is the acceptable and prevailing medical practice that it be used in the continuous mode of operation (focused or incisional) for making relatively bloodless incisions, or defocused (vaporization) for ablating a variety of superficial cutaneous disorders.

Incisional surgery with the CO₂ laser may be valuable in patients requiring anticoagulation therapy or cardiac monitoring, and patients with cardiac pacemakers. It

may also be valuable in patients undergoing scalp surgery, and in reducing bruising and postoperative swelling.

• **Conditions amenable to continuous-wave CO₂ laser treatments in the vaporization or defocused mode:**

- Actinic cheilitis and actinic keratoses
- Adenoma sebaceum
- Angiokeratomas
- Angiolymphoid hyperplasia
- Balanitis xerotica obliterans
- Basal cell carcinomas (superficial type)
- Bowenoid papulosis
- Bowen's disease
- Cherry angiomas
- Condyloma acuminatum
- Cutaneous squamous cell carcinoma in situ
- Cylindromas
- Digital mucous cysts
- Epidermal nevi (nonmelanocytic)
- Eruptive vellus hair cysts
- Granuloma faciale
- Hailey-Hailey disease
- Ingrown nails and other nail disorders requiring ablation or removal of a portion of the nail or the entire nail
- Lichen myxedematosus
- Lichen sclerosus et atrophicus
- Lymphangioma circumscriptum
- Neurofibromas
- Nodular amyloidosis
- Pearly penile papules
- Port-wine stains (adult, nodular type)
- Pyogenic granulomas
- Rhinophyma
- Sebaceous hyperplasia
- Steatocystoma multiplex
- Syringomas
- Trichoepitheliomas (perform adequate biopsy before laser treatment)
- Trichilemmomas
- Tumors of the appendages (perform adequate before laser treatment)
- Warts (refractory, periungual, plantar types)
- Xanthelasma

F. Pulsed and scanned CO₂ laser

Most conventional continuous-wave CO₂ lasers can be superpulsed, a pulsing technique in which the laser produces a train of relatively high-power, short-duration pulses. Although superpulsed CO₂ laser light can theoretically vaporize or cut tissue leaving a smaller residual zone of thermal damage than with continuous-wave CO₂ lasers, in practice this is only achieved using a spot size of 0.8 mm or smaller. Recently developed

pulsed CO₂ lasers produce short pulses (< 1 ms) at high power (> 5 J/cm²) that can remove thin layers of skin (30-50 μ m) in a single pass with little subadjacent thermal damage (50-100 μ m). Short-pulsed CO₂ lasers and some scanned CO₂ lasers are effective for resurfacing photoaged and scarred skin. The precision of these laser systems is due to the selective absorption of this wavelength of light by intracellular and extracellular water combined with the appropriate fluence to vaporize tissue and/or the appropriate pulse width to confine residual thermal damage.

- **Conditions that may be amenable to treatment with pulsed and some scanned CO₂ lasers:**

- Photoaged skin with dyspigmentation and fine, or occasionally coarse, rhytids.
- Acne scars
- Slightly raised hypertrophic scars
- Actinic keratoses
- Actinic cheilitis
- Rhinophyma
- Small tumors of the appendages, such as syringomas (perform adequate biopsy before laser treatment)
- Epidermal nevi (nonmelanocytic)
- Cosmetic surgical procedures, e.g., blepharoplasty, rhytidectomy, and hair transplantation

G. Erbium: yttrium aluminum garnet (Er:YAG) lasers

Er:YAG lasers produce short pulses (< 1 ms), at high powers (> 2.5 J/cm²), at a wavelength of 2.94 μ m which, like pulsed CO₂ lasers, can remove very thin layers of skin (25 μ m) in a single pass with even less thermal damage (5 μ m) because of highly selective absorption by intracellular and extracellular water.

- **Conditions that may be amenable to treatment with the Er:YAG laser:**

- Photoaged skin with fine rhytids
- Acne scars
- Actinic cheilitis and actinic keratoses
- Small tumors of the appendages (perform adequate biopsy before laser treatment)

IV. DIAGNOSTIC CRITERIA

A. Medical History

- Duration
- Location
- Changes that have occurred over time
- Cosmetic concerns
- Family history
- Concurrent medical problems
- Current medications
- History of isotretinoin usage
- Previous dermabrasion

- Previous cutaneous radiation
- Allergies
- History of abnormal scarring, especially keloids
- History of herpes simplex infection in area to be treated
- Skin type (facultative and acquired pigmentation)

B. Physical examination

- Description of the lesion
- Extent
- Location

C. Diagnostic tests

It is the Board's opinion that it is the acceptable and prevailing medical practice that a biopsy be performed, if the clinical appearance of the condition or lesion is insufficient to ensure an accurate diagnosis, especially with pigmented lesions.

In some conditions, the performance of a small representative test area may be necessary to accurately determine the proper laser parameters to use and tissue response in the treatment of larger areas.

V. TREATMENTS

A. Medical

In the Board's opinion, the acceptable and prevailing medical practice is that positive findings in the medical history be addressed in planning the care and management of the patient.

B. Surgical

1. Preoperative

Patient selection is very important and, in the Board's opinion, it is the acceptable and prevailing medical practice that care be taken to explain the procedure and to ensure that the patient has a complete understanding of the nature of the problem, the treatment options that are available, the risks and benefits of the various forms of treatment, the associated complications, and the potential for scarring and/or pigment changes.

In many cases, especially tattoos, port-wine stains, some pigmented lesions such as cafe au lait macules, several treatments may be required in order to achieve the best results and the greatest degree of improvement.

Pre- and post- treatment photographs may be useful in ensuring reasonable expectations.

2. Treatment techniques

In the Board's opinion, the acceptable and prevailing medical practice is to use the lowest power density or energy fluence that is consistent with a good clinical result except when using the CO₂ laser for cutting or ablation. By choosing the most appropriate wavelength and pulse characteristics that limit unwanted thermal damage, therapeutic outcome can be optimized.

3. Postoperative findings

The frequency of complications is related to the type of laser that is used and the condition that is treated.

- Occasional
 - Irregular pigmentation
 - Pain
 - Persistent erythema
 - Recurrence

- Rare
 - Bleeding
 - Failure to show satisfactory improvement
 - Infection
 - Scarring or textural changes

- Other
 - Follow-up examinations are highly encouraged and are strongly recommended.

VI. SURGICAL SETTING

In the Board's opinion, it is the acceptable and prevailing medical practice that laser surgical treatments may be performed in a physician's office, in an ambulatory surgical center, or in a hospital.

VII. DOCUMENTATION

In the Board's opinion, it is the acceptable and prevailing medical practice to appropriately document the diagnostic findings as outlined above.

In addition, it is the acceptable and prevailing medical practice that Laser parameters such as fluence, spot size, pulse duration, and wavelength be recorded and to document scanner setting when using systems with scanners.

In the Board's opinion, it is the acceptable and prevailing medical practice to obtain and document informed consent.

A. Staff

In the Board's opinion, it is the acceptable and prevailing medical practice to ensure that appropriate nursing and technical staff have documentation of laser training and safety training.

B. Procedure manuals

In the Board's opinion, it is the acceptable and prevailing medical practice to have a periodic review program in effect, which shall include review of Adequacy of Safety protocols for the laser, vacuum, and power meters.

In the Board's opinion, it is the acceptable and prevailing medical practice to have Procedure manuals for laser use and safety available in the facility.

VIII. PHYSICIAN QUALIFICATIONS

A. General

In the Board's opinion, it is the acceptable and prevailing medical practice that the physician should have:

- Completed residency training in an appropriate specialty (such as dermatology), which provides training in cutaneous surgery;
- General knowledge of basic laser physics, laser-tissue interaction, and laser safety;
- Knowledge of the special safety requirements and elements of the laser, and the prevention and management of potential complications for the specific type of laser to be used; and
- Knowledge of cutaneous anatomy and basic factors regarding cutaneous wound healing.

B. Specific

In the Board's opinion, it is the acceptable and prevailing medical practice that the physician should have:

- Laser surgery training in residency; or
- Attendance at an appropriate laser course that includes instruction in basic laser physics, laser safety, and didactic lectures on clinical applications of lasers, hands-on experience, or equivalent hands-on experience conducted under the supervision of an appropriately trained and experienced laser surgeon.

IX. NON-PHYSICIAN QUALIFICATIONS

A. General

In the Board's opinion, it is the acceptable and prevailing medical practice that a physician may delegate **certain other procedures** to certified or licensed non-physician in compliance with appropriate statutes and regulations. It is the

acceptable and prevailing medical practice that the physician supervise the non-physician to protect the best interests and welfare of each patient.

- It is the acceptable and prevailing medical practice that the supervising physician be physically present on site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed (except Laser Hair Removal).
- It is the acceptable and prevailing medical practice that it is the physician's obligation to ensure that, with respect to each procedure performed, the non-physician possesses the proper training in cutaneous medicine, the indications for the procedure, and the pre- and post- operative care involved.
- It is the acceptable and prevailing medical practice that the supervising physician perform and document an initial assessment prior to treatment and as needed during the course of therapy.
- It is the acceptable and prevailing medical practice that the non-physician satisfactorily complete a documented special education and training program on applicable, laser physics, safety, techniques and pre and post operative care and laser safety, which includes supervised practice and clinical skill competency.
- It is the acceptable and prevailing medical practice that the facility have applicable written policies and procedures.
- It is the acceptable and prevailing medical practice that continuing education for these procedures be ongoing and documented:
 - Treatment of vascular irregularities
 - Laser of facial veins
 - Treatment of leg veins by laser
 - Treatment of pigmented irregularities
 - Treatment of acne
 - Treatment of collagen stimulation
 - Treatment of microlaser peel
 - Treatment of rosacea

X. THE FOLLOWING APPLIES WITH LASER HAIR REDUCTION ONLY

- A. Treatment of laser hair reduction (**It is the acceptable and prevailing medical practice that off-site treatment may be allowed**)
- B. When physicians are involved with non-physicians in laser hair removal, it is the acceptable and prevailing medical practice that the following apply:
 - 1. There must be a responsible physician for each patient undergoing laser hair removal procedures. The responsible physician must be qualified to do the procedure themselves, i.e., appropriately trained in laser physics, safety, techniques and pre and

post operative care to perform laser hair removal using the specific device with which the patient is being treated.

2. Personnel to whom the procedure of **laser hair removal** is delegated must undergo formal training in order to ensure competence with laser hair removal. All personnel must provide written documentation of the successful completion of the following:
 - a. A didactic laser course that includes instruction in laser safety and the basic principles of laser operation. In addition, they must have documentation of training and education in the safe and effective use of each laser system to be used in the facility.
 - b. Satisfactory completion of a minimum of 30 cases under the direct supervision of the facility's medical director.
3. All personnel performing these procedures must recognize unexpected, adverse, immediate and delayed reactions to treatment, which should be part of their annual documented competence review by the medical director.

NOTE: NURSES PERFORMING LASER HAIR REMOVAL (06/04)

In June 2004, the Board responded to an opinion request on nurses performing laser hair removal.

It was the advisory opinion of the Board that the performance of laser hair removal is within the scope of nursing practice for the nurse who possesses the requisite educational preparation and current clinical competency to perform the act in a safe effective manner. The act should be performed under medical supervision. The nurse's practice should be consistent with the *Kentucky Nursing Laws* and established standards of practice, and be evidence based.

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