



Legal issues in laser operation

David J. Goldberg, MD, JD*

Skin Laser and Surgery Specialists of New York and New Jersey, Mount Sinai School of Medicine, Fordham University School of Law, New York, NY, USA

Abstract Dermatologic laser surgery is a continuously evolving field of medicine. According to the American Society for Dermatologic Surgery, in 2003, more than 100 million laser and light source cosmetic procedures were performed by its members. Procedures including hair removal and nonablative treatments, as well as removal of pigmented lesions, tattoos, and unwanted vascular lesions have revolutionized this field. With an increasing number of physicians and nonphysicians performing these procedures and with the availability of increasingly powerful laser technologies, the potential for problems and their legal consequences continue to increase. This chapter will deal with the concept of *negligence* and the potential for a resultant medical malpractice that may arise in such a setting. Inherent in this issue are the associated problems that arise when these procedures are performed by physician extenders. An understanding of the basic principals of a cause of action in medical malpractice will likely protect a physician from losing such a case in a court of law. The impact of the physician–physician extender relationship and the legal issues that arise from this relationship will also be discussed.

© 2006 Elsevier Inc. All rights reserved.

Introduction

Although legal concerns can arise in the performance of any medical procedure, they are of increasing concern in cosmetic dermatologic laser surgery. Most of the legal issues that arise in this context are in the realm of negligence.

Negligence and standard of care

Any analysis of physician negligence must first begin with a legal description of the elements of negligence. There are four required elements for a cause of action in

negligence. They are duty, breach of duty, causation, and damages. The suing plaintiff must show the presence of all four elements to be successful in her claim.¹

It is clear then that, for the plaintiff to win her negligence cause of action against the cutaneous laser surgeon, she must establish that her physician had a duty of reasonable care in treating her and had in fact breached that duty. That breach must also, however, lead to some form of damages. A mere inconvenience to the plaintiff, even in the setting of a physician's breach, will usually not lead to physician liability in a cause of action for negligence.

The duty of a physician performing cutaneous laser surgery is to perform that cutaneous laser procedure in accordance with the standard of care. By extension of this principle, any physician extender performing laser surgery will be held to the same standard as a physician. Although the elements of a cause of action in negligence are derived

* Skin Laser and Surgery Specialists of NY/NJ, 115 E. 57th St., Suite 710, New York, NY, 10022. Tel.: +1 212 750 8900.

E-mail address: drdavidgoldberg@skinandlasers.com.

from formal legal textbooks, the standard of care is not necessarily derived from some well-known textbook. It is also not articulated by any judge. The *standard of care* is defined by some as whatever an expert witness says it is and what a jury will believe. In a case against any cutaneous laser operator, the specialist must have the knowledge and skill ordinarily possessed by a specialist in that field and have used the care and skill ordinarily possessed by a specialist in that field in the same or similar locality under similar circumstances. A dermatologist, physician extender, or, for that matter, an internist performing cutaneous laser surgery will all be held to an equal standard. A failure to fulfill such a duty may lead to loss of a lawsuit by the laser operator. If the jury accepts the suggestion that the laser operator mismanaged the case and that the negligence led to damage of the patient, then liability will ensue. Conversely, if the jury believes an expert who testifies for a defendant doctor, then the standard of care, in that particular case, has been met. In this view, the standard of care is a pragmatic concept, decided case by case, and based on the testimony of an expert physician.

Where there are two or more recognized methods of diagnosing or treating the same condition, a physician does not fall below the standard of care by using any of the acceptable methods even if one method turns out to be less effective than another method. Finally, in many jurisdictions, an unfavorable result due to an “error in judgment” by a physician is not in and of itself a violation of the standard of care if the physician acted appropriately before exercising his professional judgment.

Evidence of the standard of care in a specific malpractice case includes laws, regulations, and guidelines for practice, which represent a consensus among professionals on a topic involving diagnosis or treatment, and the medical literature including peer-reviewed articles and authoritative texts. In addition, obviously, the view of an expert is crucial. Although the standard of care may vary from state to state, it is typically defined as a national standard by the profession at large.

Most commonly for litigation purposes, expert witnesses articulate the standard of care. The basis of the expert witness and therefore the origin of the standard of care is grounded in the following:

1. the witness’ personal practice,
2. the practice of others that he has observed in his experience,
3. medical literature in recognized publications,
4. statutes and/or legislative rules, and/or
5. courses where the subject is discussed and taught in a well-defined manner.

The standard of care is the way in which most of the physicians in a similar medical community would practice. It is the method by which other laser physicians deal with their daily performance of laser surgery. If, in fact, the

expert herself does not practice like most other physicians, then the expert will have a difficult time explaining why most of the medical community does not practice according to her ways.

It would seem then that, in the perfect world, the standard of care in every case would be a clearly definable level of care agreed on by all physicians and patients. Unfortunately, in the typical situation, the standard of care is an ephemeral concept resulting from differences and inconsistencies among the medical profession, the legal system, and the public.

At one polar extreme, the medical profession is dominant in determining the standard of care in the practice of medicine. In such a situation, recommendations, guidelines, and policies regarding varying treatment modalities for different clinical situations published by nationally recognized boards, societies, and commissions establish the appropriate standard of care. Even in some of these cases, however, factual disputes may arise because more than one such organization will publish conflicting standards concerning the same medical condition. Adding to the confusion, local societies may publish their own rules applicable to a particular claim of malpractice.

Thus, in most situations, the standard of care is neither clearly definable nor consistently defined. It is a legal fiction to suggest that a generally accepted standard of care exists for any area of practice. At best, there are parameters within which experts will testify. Unfortunately, because of the increased reliance on laser technology by the cutaneous laser surgeon and unrealistic expectations by the public, physicians may sometimes run the risk for being held to an unrealistic and unattainable standard of care, but in the end, it is the physician community that establishes that standard of care. For example, most would suggest that the safest technique for the removal of unwanted hair is by use of the Nd:YAG laser. A physician using a non-Nd:YAG laser or light source that is also approved by the Food and Drug Administration for the treatment of unwanted hair in darker skin types, however, may be performing laser treatment within the standard of care.

Clinical practice guidelines

American physicians have, in recent years, put forth substantial efforts toward standard setting, specifying treatment approaches to various conditions. Clinical practice guidelines, position statements, and practice guidelines, have been developed by specialty societies such as the American Academy of Dermatology, the American Society for Dermatologic Surgery, and the American Society for Lasers in Medicine and Surgery. These guidelines, as they pertain to laser surgery, stipulate who can and who cannot perform laser treatments and in what setting nonphysicians can use cutaneous lasers. The Institute of Medicine has defined such clinical guidelines as “systemically developed statements to assist practitioner

and patient decisions about appropriate health care for specific clinical circumstances.” Such guidelines represent standardized specifications for performing a procedure or managing a particular clinical problem.

Such clinical guidelines raise thorny legal issues.² They have the potential to offer an authoritative and settled statement of what the standard of care should be for a given cutaneous laser-treatable condition. Although they do not represent law, a court would have several options when such guidelines are offered as evidence. Such a guideline might be evidence of the customary practice in the medical profession.

A dermatologist, or physician extender working for that dermatologist, acting in accordance with the guidelines would be shielded from liability to the same extent as one who can establish that she or he followed professional customs. The guidelines could play the role of an authoritative expert witness or a well-accepted review article. Using guidelines as evidence of professional custom, however, is problematic if they are not necessarily consistent with prevailing medical practice.

Clinical guidelines have already had an effect according to surveys of malpractice lawyers. A widely accepted clinical standard may be presumptive evidence of due care, but expert testimony will still be required to introduce the standard and establish its sources and its relevancy.

Professional societies often attach disclaimers to their guidelines, thereby undercutting their defensive use in litigation. The American Medical Association, for example, calls its guidelines *parameters* instead of protocols intended to significantly impact on physician discretion. The American Medical Association further suggests that all such guidelines contain disclaimers, stating that they are not intended to displace physician discretion. Such guidelines, in such a situation, cannot be treated as conclusive.

Plaintiffs usually will use their own expert, as opposed to the physician's expert, to define the standard of care. Although such a plaintiff's expert may also refer to clinical practice guidelines, the physician's negligence can be established in other manners as well. These methods include (1) examination of the physician defendant's expert witness, (2) an admission by the defendant that he or she was negligent, (3) testimony by the plaintiff, in a rare case where she is a medical expert qualified to evaluate the allegedly negligent physician's conduct, and (4) common knowledge in situations where a layperson can understand the negligence without the assistance of an expert.^{3,4}

Rarely are dermatologic laser centers located within either hospitals or certified ambulatory care centers. In such situations, a plaintiff may seek hospital committee proceeding minutes about the allegedly negligent physician. The plaintiff may request production of a committee's minutes or reports, set forth “interrogatories” about the committee process and/or outcome, or seek to depose committee members about committee discussions. If the plaintiff is suing the cutaneous laser surgeon, whose work was reviewed by the committee, the discovery process may seek to confirm

the negligence of the professional or to uncover additional evidence substantiating the plaintiff's claims. Such discovery requests are often met with a claim that information that is generated within or by a hospital committee is not discoverable. Courts have ruled that the discovery protection granted hospital quality review committee records prevents the opposing party from taking advantage of a hospital's careful self-assessment.⁵ The suing plaintiff must use his or her own experts to evaluate the facts underlying the incident. It is felt by the courts that such immunity of committee proceedings protects certain communications and encourages the quality review process. External access to committee investigations, it is argued, stifles candor and inhibits constructive criticism felt to be necessary for a quality review process. Constructive, objective, peer criticism might not occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit.

When a plaintiff seeks discovery of a facility or hospital incident report rather than a committee proceeding, policy considerations are somewhat different. Incident reports kept in the medical records and possibly filed by a staff member are often more directly related to a single claim for malpractice than would general committee investigations. Courts are usually less willing to protect such incident reports.

“Off-label” uses of medical lasers

Because cutaneous laser surgery has evolved rapidly over the past decade, physicians are quick to try new innovations and experimental concepts. Such innovations partially explain the excitement of this growing field. New laser surgical procedures and the treatment of conditions that were heretofore untreatable (ie, port-wine stains and nevus of Ota) may fall into a regulatory gaps not covered by the strict regulations for the laser device itself. Licensing through the Food and Drug Administration carefully regulates medical devices such as lasers.⁶ Most human experimentation is governed by regulations of the Department of Health and Human Services. The regulations require that an institution sponsoring research must establish an institutional review board. Such an organization will evaluate research proposals before any experimentation begins to determine whether human subjects might be “at risk” and, if so, how to protect them.

It is not usually difficult to determine whether a new laser is being used experimentally. It is, however, very difficult to determine whether an actual given laser procedure is experimental. Laser surgeons often view themselves as artists in addition to scientists, custom tailoring a treatment of a particular condition. Such approaches can lead to a bad result with variable outcomes in the courts. A dermatologist using a standard laser hair removal system around the eyelashes with resultant damage to the iris will be

questioned. A laser surgeon who chooses to use a carbon dioxide laser, rather than a scalpel, to perform a circumcision procedure, with a resultant complication leading to penile amputation would have problems suggesting that her medical experimentation conformed to reasonable standard of care. Another dermatologist, however, who chooses, after appropriate informed consent, to use the same laser, rather than a scalpel, for excision of a nevus, with resultant significant scarring might be considered an innovator rather than an experimenter. Such a physician would be no more liable for straying from his duty than the surgeon who might use a standard scalpel, with the same complication, for the same procedure.

In fact, most clinical innovation falls between standard practice and experimental research. Much of this innovation is unregulated by the government. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has suggested that any "radically new" procedure should be made the object of formal research at an early stage to determine whether such a procedure is safe and effective. It can be argued that some of the cutaneous laser procedures that have evolved, using already Food and Drug Administration-cleared laser devices, might be considered radical; most clearly are not.

Use of physician extenders

These issues become magnified when being performed by a physician extender. The issue as to who can perform those

procedures is governed by state law. Such law varies from state to state and will always outweigh a more liberal society guideline. Where the nonphysician is legally performing laser treatments and where that physician extender is performing within the scope of her duty, the extender and the physician will be found liable for physician extender caused negligence.

In the end, it is often difficult to predict in any given malpractice cause of action against a dermatologist what the ultimate outcome will. A clear understanding of the aforementioned principles, however, will markedly decrease the chance of a physician losing any negligence cause of action brought against her.

The cutaneous operator (physician or nonphysician) is expected to perform a laser procedure in a manner of a reasonable physician. He need not be the best in his field; he need only perform the procedure in a manner that is considered by an objective standard as reasonable.

References

1. Furrow BF, Greaney TL, Johnson SH, et al. *Liability in health care law*. 3rd ed. St Paul (Minn): West Publishing Co; 1997.
2. Hyams AL, Shapiro DW, Brennan TA. Medical practice guidelines in malpractice litigation: an early retrospective. *J Health Polit Policy Law* 1996;21:289.
3. *Lamont v. Brookwood Health Service, Inc*, 446 So.2d 1018 (Ala. 1983).
4. *Gannon v. Elliot*, 19 Cal. App 4th 1 (1993).
5. *Coburn v. Seda*, 101 Wash.2d 270 (1984).
6. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. s301.