

The Practice of Laser Acupuncture



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Am I permitted to use therapeutic lasers in my state? How do I comply with FDA guidelines and other legal requirements? What should I look for to ensure that I choose the right laser? How do I acquire knowledge and proficiency? Attempting to answer these and other practical questions is the focus of this ninth article in the series.

FDA Guidelines

In contrast with surgical lasers which may have outputs in the tens to hundreds of watts and considerable associated risk, laser therapy¹ is given at low output power, usually less than half a watt. FDA has described these lasers as ‘non-significant risk devices.’²

One would think that devices acknowledged as ‘non-significant risk’ should be easily accessible to licensed practitioners who might wish to use them. However, FDA has also categorized almost all currently manufactured therapeutic lasers as ‘investigational’. ***Practically speaking, if one wishes to use most of the devices currently being manufactured, two conditions must be met: 1) laser therapy must be within one’s scope of practice or at least not excluded, and 2) therapeutic lasers must be used in research according to specific guidelines.***

¹ Laser therapy is the most common term for the therapeutic administration of laser light at low intensity. Low level laser therapy and low intensity laser therapy are other terms which have been used.

² From <http://www.fda.gov/oc/ohrt/irbs/devices.html#nonsig>

In order to find out if laser therapy is permitted under one's license, the reader should study a copy of his or her practice act and board rule. This is usually available online. If your scope of practice does not include laser therapy, please consider becoming active in your state association to seek changes in your statute or board rule.

What is an Independent Investigational Review Board (IIRB)?

As most therapeutic lasers remain 'investigational', their use requires oversight. The primary purpose of an Independent Investigational Review Board or IIRB is to protect the welfare and rights of human subjects voluntarily participating in research. Its secondary purpose is to evaluate and approve the initiation of appropriate investigational protocols and conduct periodic review of that research.

A review board may be known as an Independent Investigational Review Board (IIRB) or an Institutional Review Board depending upon whether it is autonomous or affiliated with a school or other organization. Although at first glance reporting and other requirements may seem complicated, in my experience they are actually fairly easily met, and the freedom to use the laser of one's choice will make the extra effort well worth it.

Florida and Massachusetts have IIRBs specifically for licensed acupuncture physicians, and there are also other review boards which will accept practitioners from many states. If you decide to purchase a therapeutic laser, its manufacturer is likely to be able to help you to find an IIRB. To learn more about IIRBs, please visit the FDA website, <http://www.fda.gov/oc/ohrt/irbs/default.htm>.

Other Legal Requirements

Each state is different, and it is up to anyone who wishes to practice with therapeutic lasers to find out what the requirements are and comply with them. For example, the Florida Board of Acupuncture stipulates that it must be noticed in writing by any licensed acupuncture physician who plans to use a therapeutic laser 14 days in advance along with proof of compliance with FDA guidelines. Florida also requires that all therapeutic lasers must be registered with its Department of Health, Radiation Control Office. Your

state board is likely to be able to help you, but you may also need to contact a number of state agencies and/or other resources to research what is required.

Which Laser Should I Choose?

All lasers are not created equal. What are the power, wavelength and other parameters which will best meet your needs? Take the time to research these issues before making a purchase. Too many practitioners have confessed to me that they paid for a device without a clear understanding of its capability or their own needs only to learn later that what they had was inadequate, often at a cost of many thousands of dollars.

Light emitting diodes (LEDs) are sometimes marketed as lasers. Do not be dazzled or misled. Lasers will give superior results in almost all instances. Devices which mix laser diodes and LEDs are also not recommended. A probe with a single laser diode of the appropriate wavelength and power will be the best choice for most practitioners.

FDA has approved a few therapeutic lasers for limited purposes. How effective are these devices? As of the time of this writing, any lasers which have been approved will be less than optimal for most applications in my opinion because they are relatively low powered. It is my experience that an infrared, Class 3b laser at or near the maximum permissible power output of 500 milliwatts is likely to give the best results in most instances. Although oversight by a review board will be necessary, the improved clinical outcomes which may follow will more than make up for the extra effort.

Just as in choosing any equipment, check the reputation of the device and its manufacturer for service and reliability. Lasers diodes lose power over time and require periodic servicing. One should take into consideration turn around time and the cost of this service. The device you are considering should have a power meter. If a laser probe runs hot, it may be at or near its design capacity, and its life expectancy is likely to be far less than a probe which runs cooler.

How do I acquire knowledge and proficiency in laser therapy?

Study the literature. Take a seminar. Seek a thorough grounding in both theory and hands-on, clinical training. Learn what you can treat. A good resource in this regard is www.healinglightseminars.com. Click on 'Laser Research Library' and then on any condition or topic of interest.

Just as patients have asked you to explain acupuncture, they will want to know how laser therapy works. As with any modality, the deeper your understanding, the better you will be able to treat.

Commentary

An adverse reaction to laser therapy has never been documented. Yet access has been restricted. In contrast, the pharmaceutical drug, Vioxx, may soon be on the market again despite the fact that David Graham, former associate director of FDA's Office of Drug Safety, believes that it may have killed as many as 55,000 people (a number greater than all U.S. casualties in the Vietnam War).

Invitation to attend NAALT 2005

The North American Association for Laser Therapy's annual conference begins Friday, May 20, 2005 and runs through Sunday, May 22, 2005 at Nova Southeastern University, 3301 College Ave., Ft. Lauderdale, Florida.

This year's emphasis will be on clinical applications of therapeutic lasers and other forms of phototherapy. The tentative program includes presentations by Drs. James Oschmann, Shimon Rochkind, Mary Dyson, Margaret Naeser, Paul Bradley, Jeff Spencer, Paul Nemenov, Chukuka Enwemeka, Cesar Migliori, and Raymond Lanzafame.

Anyone interested in laser therapy is invited to attend. If you would like more information, please visit www.naalt.org, or write to NAALT, 188 Sherwood Drive, Waynesboro, VA 22980.

References

1. Laser therapy is the most common term for the therapeutic administration of laser light at low intensity. Low-level laser therapy and low-intensity laser therapy are other terms that have been used.

2. www.fda.gov/oc/ohrt/irbs/devices.html#nonsig.

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