Lasers in Physical Therapy

A NEW ADDITION
(SINCE 2004)
TO
PHYSICAL AGENTS & THERAPEUTIC INTERVENTIONS

Laser

- **Laser** is an acronym for:
  - Light
  - Amplification from the
  - Stimulated
  - Emission of
  - Radiation

“As long as I am alive I will be thinking about light.”
Laser

• What is meant by stimulated emission of radiation?
  ○ Laser light is created by a specific process within a laser device to cause the controlled emission of radiation in the form of light.
  ○ Lasers used in physical medicine emit low levels of light, in the milli Watt range which is much less than what is emitted from light sources within most rooms.

1 milliWatt = 1/1000th of 1 Watt

• If the light is really “stimulated emission of radiation” then am I at risk of exposure to that radiation?
  ○ The radiation is controlled and at a milli Watt level, which is much less than the 70-100 Watt level of the light in the room you are now sitting in.
A laser is made up of an optical cavity or chamber that contains an active medium for which the laser is named. The chamber has mirrors at either end that are perfectly parallel to each other, within a single wavelength of light. One of the mirrors is partially open.

Electricity or energy is added to the medium which excites it.
Laser

- The active medium’s atoms are then reflected back and forth across the mirrors within the chamber. This causes more excitation of the atoms within the medium.

Laser

- Laser light is then emitted through the partially reflective end of the mirror.
Laser

- The light production occurs due to the following:

  ![Diagram of laser light production]

  1. Electron is pumped to a higher energy level.
  2. Pumping level is unstable, so the electron quickly jumps to a slightly lower energy level.
  3. Electron relaxes to a lower energy state and releases a photon.
  4. Light and an electron in an excited energy level...
  5. ...produces two photons of the same wavelength and phase.
  6. Mirror reflects photons.

Laser

- Due to the specific nature of how laser light is produced it also has specific properties:
  - Monochromatic
  - Coherent
  - Parallel
• **Monochromatic**
  - Monochromaticity refers to the color or wavelength of laser light
    - Laser is produced from one **active medium** unlike white light which is produced from many gases and solids
    - White light is made up of a rainbow of colors
    - Laser light is one color, one wavelength
Coherent & Parallel

- Due to the common wavelength of laser light, the phase of each of the wavelengths is also common.
- Light travels in sine waves in phase relationship with one another with peaks and valleys precisely coinciding and reinforcing each other.

If all of the wavelengths are the same, then it’s easy for them to occur together.

With white light, it’s impossible since the wavelengths are all different.
Laser

- Coherent light sources are powerful in that they are similar to an army regiment marching in cadence crossing a bridge.
- All of the waves of energy hit at the same time amplifying the energy rather than a randomized array of energy.

Laser

- Theorized Mechanisms of Action
  - Phospho-lipid Gate and coherent Light
    - The cell membrane “oscillates” due to the coherence of the waveforms and thus increases cell membrane permeability
Laser

- Photosensitivity of Prostaglandin E
  - A pain and inflammatory mediator is converted into a vasodilator which then helps increase circulation in the area and decrease discomfort
  - Prostacycline-endoperoxide

Beam Adherence & Phase relationship

- Since the light is monochromatic, it has only one wavelength
  - All of the energy is also exactly in phase
  - This provides phenomenal “push” due to the phase relationship
Laser

- Coherent & Parallel
  - Light from most sources spreads out as it travels meaning that there is less light the greater the distance from light source.
  - Laser light travels as a parallel beam, spreading very little.

- Laser light was initially used to measure the distance to the moon.
- A mirror was placed on the moon and a laser was pointed at the moon. The time for the beam to return to the Earth was recorded and since the speed of light is known, the distance could be calculated.
Characteristics of Laser

- Why do you care about divergence?
  - Precision is needed when applying laser to a treatment area
  - Have you ever received a speeding ticket?
    - The speed of light is well documented entity...

History of the use of Light

- Einstein
  - A photon of light is given off with every mitotic cellular division.
History of the Use of Light

• **1940s**
  - Patients who are allowed to experience daylight tend to recover from depression more quickly.
  - Would you want to be treated in this ward?

• **Late 20th century**
  - Some patients experience an affective disorder that is directly related to a lack of light that can be reversed by daily exposure to a lamp during the winter months.
History of the Use of Light

• The villi and micro villi within the organelles of our cells act as fiber-optics and carry light impulses but we have not identified the purpose of the system in-detail to date.

Laser

• So how long have lasers been around?
  - Physicist Gordon Gould invented the laser in 1958
  - The first working model was built in 1960
Lasers in Medicine

- They have been used in Europe for more than 40 years.
- Cold lasers were first introduced in the USA in the early 1980s.
- Applications
  - Dermatology
  - Surgery
  - Ophthalmology
  - Physical Med & Rehab

Lasers in Rehabilitation

- First Introduced in the early 1980s
  - Medical Devices are regulated by the Food and Drug Administration
    - Prior to their use on patients, companies must submit the appropriate documentation that satisfies the scientists at the FDA that the product meets the standards for
      - SAFETY & EFFICACY
    - If the device has not met those standards yet, then it is said to be “Investigational”
Laser Safety

• Laser labeling

Lasers & the FDA

• Step 1: Investigational Device Exemption
  - Until safety and efficacy have been substantiated
    o Must have informed consent of patient
    o Cannot make specific claim regarding outcome
    o Cannot bill for use of device (time involved is OK)
    o Must be part of an Institutional Review Board (IRB) approved protocol for application
Lasers & the FDA

- Step 2: Approval
  - Only for the specific protocol
  - Only for the application as described in the protocol
    - Diagnosis specific

Lasers & the FDA

- Laser is the first device to be put to this type of scrutiny.
- The law requiring these steps came into effect in 1976.
Lasers & the FDA

- Lasers were introduced in the US in 1982.
- All other physical agents have been “grandfathered”.

Major Categories of Laser Use

- Alignment
- Annealing
- Balancing
- Biomedical
  - Cellular research
  - Dental
  - Diagnostics
  - Dermatology
  - Ophthalmology
  - Surgery
- Communications
- Construction
  - Alignment
  - Ranging
  - Surveying
**Major Categories of Laser Use**

**OSHA**

- Cutting
- Displays
- Drilling
- Entertainment
- Heat treating
- Holography
- Information handling
  - Copying
  - Displays
  - Plate making
  - Printing
  - Reading
  - Scanning
  - Typesetting
  - Videodisk
  - Marking

**Major Categories of Laser Use**

**OSHA**

- Laboratory instruments
- Metrology
- Plasma diagnostics
- Spectroscopy
- Velocimetry
  - Special photography
  - Scanning microscopy
- Military
  - Distance ranging
  - Rifle simulation
  - Weaponry
- Nondestructive training
- Scanning
- Sealing
- Scribing
- Soldering
- Welding
Lasers are classified into four broad areas depending on the potential for causing biological damage.

When you see a laser, it should be labeled with one of these four class designations:

- **Class I** These lasers cannot emit laser radiation at known hazard levels.
- **Class I.a** This is a special designation that applies only to lasers that are "not intended for viewing," such as a supermarket laser scanner. The upper power limit of Class I.A. is 4.0 mW.
Laser Classifications

- **Class II** These are low-power visible lasers that emit above Class I levels but at a radiant power not above 1 mW.
  - The concept is that the human aversion reaction to bright light will protect a person.

Laser Classifications

- **Class III.a** These are intermediate-power lasers (cw: 1-5 mW), which are hazardous only for intrabeam viewing. Most pen-like pointing lasers are in this class.
- **Class III.b** These are moderate-power lasers.
Laser Classifications

- **Class IV** These are high-power lasers (cw: 500 mW, pulsed: 10 J/cm² or the diffuse reflection limit), which are hazardous to view under any condition (directly or diffusely scattered), and are a potential fire hazard and a skin hazard. Significant controls are required of Class IV laser facilities.

Summary of Basic Biological Effects of Light

<table>
<thead>
<tr>
<th>Photobiological Spectral Domain</th>
<th>Eye Effects</th>
<th>Skin Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultraviolet C (0.200-0.280 μm)</td>
<td>Photokeratitis</td>
<td>Eythema (sunburn) Skin cancer</td>
</tr>
<tr>
<td>Ultraviolet B (0.280-0.315 μm)</td>
<td>Photokeratitis</td>
<td>Accelerated skin aging Increased pigmentation</td>
</tr>
<tr>
<td>Ultraviolet A (0.315-0.400 μm)</td>
<td>Photochemical UV cataract</td>
<td>Pigment darkening Skin burn</td>
</tr>
<tr>
<td>Visible (0.400-0.780 μm)</td>
<td>Photochemical and thermal retinal injury</td>
<td>Photosensitive reactions Skin burn</td>
</tr>
<tr>
<td>Infrared A (0.780-1.400 μm)</td>
<td>Cataract, retinal burns</td>
<td>Skin burn</td>
</tr>
<tr>
<td>Infrared B (1.400-3.00 μm)</td>
<td>Corneal burn, aqueous flare, IR cataract</td>
<td>Skin burn</td>
</tr>
<tr>
<td>Infrared C (3.00-1000 μm)</td>
<td>Corneal burn only</td>
<td>Skin burn</td>
</tr>
</tbody>
</table>
Types of Lasers

- **Semiconductor lasers**, sometimes called diode lasers, are not solid-state lasers. These electronic devices are generally very small and use low power. They may be built into larger arrays, such as the writing source in some laser printers or CD players.

- There are many different types of lasers. The laser medium can be a solid, gas, liquid or semiconductor. Lasers are commonly designated by the type of lasing material employed:
  - **Solid-state lasers** have lasing material distributed in a solid matrix (such as the ruby or neodymium : yttrium-aluminum garnet “Yag” lasers). The neodymium-Yag laser emits infrared light at 1,064 nanometers (nm). A nanometer is 1x10^-9 meters.
Types of Lasers

- **Gas lasers** (helium and helium-neon, HeNe, are the most common gas lasers) have a primary output of visible red light.
- CO2 lasers emit energy in the far-infrared, and are used for cutting hard materials.

Types of Lasers

- **Excimer lasers** (the name is derived from the terms *excited* and *dimers*) use reactive gases, such as chlorine and fluorine, mixed with inert gases such as argon, krypton or xenon.
- When electrically stimulated, a pseudo molecule (dimer) is produced.
- When lased, the dimer produces light in the ultraviolet range.
Types of Lasers

- **Dye lasers** use complex organic dyes, such as rhodamine 6G, in liquid solution or suspension as lasing media.
- They are tunable over a broad range of wavelengths.

FDA Center for Devices and Radiological Health Performance Requirements.

Under the requirements of the FLPPS, the manufacturer is first required to classify the laser as either a

- Class-I
- Class-I.A.
- Class-II
- Class-III A, Class-III B, or
- Class-IV laser product

and then to certify (by means of a label on the product) as well as submit a report demonstrating that all requirements (performance features) of the compliance standard are met.
### Laser Classifications - Summary of Hazards (OSHA)

<table>
<thead>
<tr>
<th>Class</th>
<th>UV</th>
<th>VIS</th>
<th>NIR</th>
<th>IR</th>
<th>Direct Ocular</th>
<th>Diffuse Ocular</th>
<th>Fire</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
<td>no</td>
<td>no</td>
<td>No</td>
</tr>
<tr>
<td>IA</td>
<td>--</td>
<td></td>
<td></td>
<td>x</td>
<td>Only after 1000 sec</td>
<td>no</td>
<td>No</td>
</tr>
<tr>
<td>II</td>
<td>--</td>
<td>x</td>
<td></td>
<td>--</td>
<td>Only after 0.25 sec</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>IIIA</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>yes</td>
<td>no</td>
<td>No</td>
</tr>
<tr>
<td>IIIB</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>yes</td>
<td>Only when laser output is near class IIIB limit of 0.5 Watt</td>
<td>No</td>
</tr>
<tr>
<td>IV</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

**Key:**
- x = indicates class applies in wavelength range.
- * = class IA applicable to lasers “not intended for viewing” only.
- **= CDRH Standard assigns class IIIA to visible wavelengths only. ANSI Z 136.1 assigns Class IIIA to all wavelength ranges.

### FDA Center for Devices and Radiological Health Performance Requirements.

- The CDRH of the Department of Health and Human Services was chartered by Congress to standardize the manufacture of lasers in interstate commerce after **August 2, 1976**.
- CDRH also has the responsibility for enforcing compliance with the medical devices legislation.
- All manufacturers of surgical lasers must obtain pre-market approval of their devices through the CDRH.
The FDA sanctions the exploratory use of lasers for specific procedures through a process known as an Investigational Device Exemption (IDE).

Approval of an IDE permits the limited use of a laser expressly for the purpose of conducting an investigation of the laser's safety and effectiveness.

Once an IDE has been prepared and approved by the CDRH, the manufacturer may then actively market the laser for that specific medical or surgical procedure.

The FDA/CDRH Federal Laser Product Performance Standard (FLPPS) regulates the manufacturer of commercial laser products, not the user.

The standard does not contain specific design specifications, but is a conceptual, performance standard which the designer of laser products must consider.

The intent is to insure laser product safety.
FDA Center for Devices and Radiological Health
Performance Requirements.

- FLPSS is applicable to lasers or laser systems sold by a company within or imported into the U.S.
- In some cases it can also apply when a laser or laser system is transferred within a company for internal use within the U.S.
- The compliance procedure requires implementation of the procedures and requirements as set forth in the *U.S. Federal Laser Product Performance Standard: 21 CFR Part 1000 [parts 1040.10 and 1040.11]*.

Specific performance features include:
- protective housing;
- protective housing warning labels and logotype labels;
- product identification label and certification statement;
- safety interlocks;
- emission indicator;
- remote interlock connector;
FDA Center for Devices and Radiological Health
Performance Requirements.

- Specific performance features include:
  - key control;
  - beam attenuator;
  - specification of control locations;
  - viewing optic limitations;
  - scanning beam safeguards; and
  - manual reset of beam cutoff.

Why should you care?

- Lasers are the first devices to be subject to the FDA requirements!
  - Other devices that we commonly use in physical therapy were:
    - “grandfathered” in
  - We now have to have evidence that devices are:
    - Safe and effective for specific applications BEFORE they are marketed
Potential Benefits of Laser

- ATP production
- Collagen Synthesis
- Wound healing
- Pain reduction

...and there is no sensation to the patient except possibly the sensation of a slight breeze.

Lasers Today

- Recently considered appropriate by the FDA and approved for the treatment of carpal tunnel syndrome

- However: CIGNA, one of the larger insurance companies will not reimburse for treatment with laser.
Lasers Today

- Method of Treatment
  - Depth of penetration
  - Treatment time calculation
    - Power
    - Treatment area size
    - Wavelength of the laser

Laser

- Precautions
  - Treating infected wounds
    - Use sterile technique
  - Treating near the gonads
  - Treating patients with cognitive/language difficulties
Laser

- **Contraindications**
  - Direct treatment of the eye
  - Irradiation of the fetus or over the abdomen of a pregnant female
  - In the presence of active carcinoma
  - Over an area of acute hemorrhage
  - Patients who are hypersensitive to light

---

Laser Applications

- Tattoo removal
- How Do Lasers Remove Tattoos?
Laser Applications

- Lasers work by producing short pulses of intense light that pass harmlessly through the top layers of the skin to be selectively absorbed by the tattoo pigment.
- This laser energy causes the tattoo pigment to fragment into smaller particles that are then removed by the body's immune system.

Laser Applications

- Researchers have determined which wavelengths of light to use and how to deliver the laser's output to best remove tattoo ink.
Laser Applications

• If you're wondering if the laser might also remove normal skin pigment, don't worry.

Laser Applications

• The laser selectively targets the pigment of the tattoo without damaging the surrounding skin.
Laser Applications

Lasers in PM & R

- Carpal Tunnel Syndrome
  - Reduction in pain and inflammation
- Low Level Laser Therapy (LLLT)
  - Technology Assessment

Carpal Tunnel treatment without surgery!
Where do we go from here?

- IF someone attempts to sell you something that sounds too good to be true, chances are, it is.
- However; keep your eyes and ears open, you could be surprised in the future.

It looks like a lot of ducks to me, why did they say it was a lion?