

# **‘Is cold laser therapy within the scope of practice of a Chiropodist?’**

**Members:**

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## **PURPOSE:**

The Registrar of the College of Chiropractors of Ontario referred the following question to the Technical Committee of the College of Chiropractors, in order to respond to an enquiry submitted:–*Can you please advise if cold laser therapy is within the scope of practice of a chiropractor?*

The Committee deemed the term ‘Chiropractor’ in reference to the question to be a ‘registered member of the College of Chiropractors of Ontario’ including BOTH the Chiropractor and Podiatrist class of registrant.

## **EXECUTIVE SUMMARY**

### **Definition of Cold Laser**

- The term cold laser therapy is used interchangeably with bio-stimulation, photobiomodulation and Low Level Laser Therapy (LLLT). Cold laser therapy for the purpose of this submission is defined as *‘the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000nm, power from 5–500 milliwatts’*. The power densities used are lower than those needed to produce heating of tissue.

### **Potential applications of Cold-Laser Therapy within the practice of chiropractic in Ontario**

- Cold laser therapy is used for three main purposes: to promote wound healing, tissue repair, and the prevention of tissue death; to relieve inflammation and oedema because of injuries or chronic diseases; as an analgesic and a treatment for other neurological problems. These applications appear in a wide range of clinical settings, ranging from dentistry, dermatology, rheumatology and physiotherapy

### **Application of Laser Therapy under *Regulated Health Professions Act (RHPA) 1991***

- The Regulation under the RHPA that refers to controlled acts and identifies the forms of energy that are prescribed for the purpose of paragraph 7 of subsection 27 (2) of the Act. This list is inclusive of all forms of energy that fall under the controlled acts related to applying or ordering the application of a form of energy. If an intervention or test is not listed in this Regulation, then it is not considered a form of energy according to the Regulation, and therefore not considered a controlled act. There are many different

forms of energy that are not listed as controlled acts in the Regulated Health Professions Act, 1991. In instances where a specific form of energy is not listed in legislation, the RHPA does not restrict how or by whom that form of energy may be applied.

- A member of the College of Chiropractors of Ontario is exempt from subsection 27 (1) of the Act for the purpose of applying electricity for electrocoagulation or fulguration. O. Reg. 107/96, s.\_2. No differences related to the application of energy are present between Podiatry and Chiropractic class of members

### **Conclusion / Recommendation to Council of College of Chiropractors of Ontario**

The Technical Committee concludes:

- Cold Laser Therapy /LLLT is within the scope of practice of a registered member of the College of Chiropractors of Ontario.
- Executive and Council should proactively consider the production of Guidelines to members about the safe and appropriate use of ALL classes of Lasers by its members.

### **Core points identified, and considered by the Technical Committee:**

- What is the definition of 'Cold Laser Therapy'?
- What are the potential applications of 'Cold Laser Therapy' within the practice of Chiropractic?
- According to the Regulated Health Professions Act 1991, is the use of a 'Cold Laser' a Controlled Act within Ontario?
- If the use is a Controlled Act is it authorized as an exemption for a registered member of the College of Chiropractors of Ontario?

### **Methodology**

A literature review and detailed assessment of the available body of research that addressed the Core points was performed using Medline, Google Scholar and web based search engines. Data was distributed to committee members for analysis and reviewed during a teleconference.

## Glossary (1)

**ANSI:** The American National Standards Institute - a private, non-profit organization that administers the US voluntary standardization and conformity assessment system.

**Beam:** the pulsed or continuous output from a laser.

**Coherent:** a beam of light characterized by a fixed phase relationship or single wavelength (i.e. monochromatic).

**Cold Laser Therapy:** also referred to as LLLT, low-power laser therapy (LPLT), low-intensity laser and low energy laser therapy. Utilizes red-beam or near-infrared lasers with a wave-length between 600 and 1000nm, power from 5–500 milliwatts. Cold laser therapy does not induce heating in tissue.

**Danger:** indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury e.g. retinal burn from direct exposure to the laser beam.

**Diffuse reflection:** change of the spatial distribution of a beam of radiation when it is reflected from a rough surface in many directions.

**Direct beam:** the output beam from the laser, prior to any reflection or absorption.

**Electromagnetic radiation:** the flow of energy at the speed of light in the form of electric and magnetic fields. Gamma rays, X-ray, ultraviolet, visible, infrared, and radio waves occupy various portions of the electromagnetic spectrum and differ only in frequency, wavelength and photon energy.

**Infrared radiation (IR):** invisible radiation wavelengths from about 700 nm to 1,000,000 nm (1 millimeter). Hair removal lasers operate between 700 and 1400 nm.

**Irradiance:** the radiant power incident per unit area upon a surface, expressed in W/cm<sup>2</sup> (Symbol: E).

**Joule (J):** the unit used to measure the energy of a laser pulse.

**kW/cm<sup>2</sup>:** a kilowatt per square centimeter [see Watt].

**Laser:** acronym for **L**ight **A**mplification by **S**timulated **E**mission of **R**adiation.

**Laser controlled area:** an area that is appropriately enclosed so that no laser radiation above the maximum permissible exposure inadvertently escapes to injure unsuspecting persons. This area is subject to the control and supervision of the laser safety officer and must contain the nominal hazard zone (NHZ) unless special safety features are incorporated into the room.

**Laser personnel:** those who work routinely in the laser environment and are normally fully protected by engineering controls and/or administrative procedures (i.e. operators or service providers).

**Laser safety officer (LSO):** a person who is authorized by management (business owner) to be responsible for the laser safety program in the facility. The LSO is responsible for monitoring and overseeing the control of laser hazards.

**Light:** electromagnetic radiation having wavelengths between approximately 400 to 700 nm and which are perceptible to human vision (aka “visible light”).

**Maximum Permissible Exposure (MPE):** the level of laser radiation to which an unprotected person may be exposed without adverse biological changes in the eye or skin i.e. injury.

**Nanometers (nm):** a unit of length equal to one thousand millionth of a meter (10<sup>-9</sup> m) and used in the measure of wavelengths of optical radiation i.e. ultraviolet, visible and infrared radiation.

**Nominal Hazard Zone (NHZ):** the space within which the level of the direct, reflected, or scattered radiation during normal operation exceeds the applicable maximum permissible exposure. This zone is usually smaller than and within the laser controlled area.

**Optical density (OD):** a material's ability to absorb laser radiation, as used in protective eyewear.

**Radiation:** Emission and propagation of energy in the form of particles or waves.

**Retina:** The delicate multilayered light-sensitive membrane lining the inner posterior chamber of the eyeball that contains the rods and cones, and is connected by the optic nerve to the brain.

**Specular reflection:** change of the spatial distribution of a beam of radiation when it is reflected from a mirror-like surface in one direction.

**Visible light:** electromagnetic radiation having wavelengths between approximately 400 and 700 nm and which are perceptible to human vision (aka "light").

**Wavelength:** The distance between one peak or crest of a wave of light or other electromagnetic radiation and the next corresponding peak or crest.

**Watt/cm<sup>2</sup>:** a watt per square centimetre.

**Watt (W):** a unit of power equal to one joule per second.

### Laser classifications (2)

**Class 1 Laser** equipment emitting radiation that is not considered hazardous even for long-term exposure. These lasers do not require hazard-warning labelling. Examples include positioning and alignment lasers, low-level laser therapy and home-use lasers.

**Class 1M Laser** equipment emitting radiation that is not considered hazardous for the naked eye even for long-term exposure.

**Class 2 Laser** equipment emitting visible radiation in the wavelength range from 400 nm to 700 nm that is considered safe for exposures of duration less than 0.25 s. Examples include alignment lasers used in aiming invisible radiation of CO<sub>2</sub> and Nd:YAG lasers.

**Class 2M Laser** equipment emitting visible radiation in the wavelength range from 400 nm to 700 nm that is considered safe for the naked eye for exposures of duration less than 0.25 s.

**Class 3R Laser** equipment emitting radiation that can exceed the MPE when viewed directly but with low risk of permanent eye injury.

**Class 3B Laser** equipment emitting radiation considered hazardous to the skin and eyes from direct exposure or a specular reflection.

**Class 4 Laser** equipment emitting radiation considered hazardous to the skin and eyes from direct exposure or a specular or diffuse reflection.

### Introduction

Cold laser therapy, came into being soon after the invention of the ruby laser in 1960, and the helium–neon (HeNe) laser in 1961. (4) In 1967, Endre Mester, applied his early animal studies' findings to human patients, using lasers to treat patients with non-healing skin ulcers Cold Laser/ LLLT has now developed into a therapeutic procedure that is used in three main ways: to reduce inflammation, edema, and chronic joint disorders<sup>9,18,40</sup>; to promote healing of

wounds, deeper tissues, and nerves, and to treat neurological disorders and pain. Cold laser therapy involves exposing cells or tissue to low levels of red and near infrared (NIR) light. It is also referred to as “low level laser therapy” because of its use of light at energy densities that are low compared to other forms of laser therapy that are used for ablation, cutting, and thermally coagulating tissue.

Although cold laser therapy is now used to treat a wide variety of ailments, it remains controversial as a therapy.

It has been called many names over the years including biostimulation, LLLT, cold laser therapy, and more recently photobiomodulation. Low level lasers (mostly diode lasers in the 10-200 milliwatt range) have been the primary instruments but there are also non-laser light emitting diodes (LED's) and other light sources that are used. (3)

LLLT is used for three main purposes: to promote wound healing, tissue repair, and the prevention of tissue death; to relieve inflammation and oedema because of injuries or chronic diseases; and as an analgesic and a treatment for other neurological problems. These applications appear in a wide range of clinical settings, ranging from dentistry, dermatology, rheumatology and physiotherapy. Low level laser therapy does not induce heating in tissue like surgical or aesthetic lasers (3,4)

### **Definition of Cold Laser**

#### **Cold laser**

*A hand-held, nonsurgical laser using photobiostimulation, which received FDA approval for treating carpal tunnel syndrome. Benefits claimed for cold lasers include increased collagen production, nerve regeneration, bone and tissue repair, vasodilation, enzyme response, cell metabolism, cell membrane potential, pain threshold, and reduced inflammatory duration and oedema. (5)*

#### **Low-level laser therapy (LLLT)**

*Adjunctive therapeutic use of a low-level infrared laser that amplifies light energy (photons) emitted as radiant energy for absorption into tissues used to enhance wound healing and pain management after musculoskeletal injury. (6)*

Hoon et al (4) state that LLLT is also known as “cold laser” therapy as the power densities used are lower than those needed to produce heating of tissue. It was originally believed that LLLT or photobiomodulation required the use of coherent laser light, but more recently, light emitting diodes (LEDs) have been proposed as a cheaper alternative. A great deal of debate remains over whether the two light sources differ in their clinical effects.

Cigna recognize that cold laser therapy is also referred to as LLLT, low-power laser therapy (LPLT), low-intensity laser and low energy laser therapy. (7)

Aetna also notes that the term cold laser (or class III laser) is used interchangeably with low-energy laser or low level laser therapy (LLL). Aetna define, low energy laser therapy uses as 'irradiation intensities that induce minimal temperature elevation (not more than 0.1 to 0.5°C), if any. For practical purposes, this restricts treatment energies to a few J/cm<sup>2</sup> and laser powers to 500 mW or less'. (8)

This appears consistent with CIGNA that classifies Low-level laser therapy as 'the use of red-beam or near-infrared lasers with a wave-length between 600 and 1000nm, power from 5–500 milliwatts. (7)

In contrast, lasers used in surgery typically use 300 watts' High-power lasers (class IV therapeutic lasers; not to be confused with class IV surgical lasers) have power output of up to 7,500 mW; and supposedly offer more power, deeper penetration (can penetrate up to 10 cm<sup>2</sup> instead of 0.5 to 2.0 cm<sup>2</sup> for class III lasers) and a larger surface treatment area (cover up to 77 cm<sup>2</sup> instead of 0.3 to 5.0 cm<sup>2</sup> for class III lasers). (7)

LLL remains poorly understood, so its use is largely empirical. A large number of parameters such as the wavelength, fluence, power density, pulse structure, and timing of the applied light may be chosen for each treatment. A less than optimal choice of parameters can result in reduced effectiveness of the treatment, or even a negative therapeutic outcome. As a result, many of the published results on LLL include negative results because of an inappropriate choice of light source and dosage. This choice is particularly important as there is an optimal dose of light for any particular application, and doses higher or lower than this optimal value may have no therapeutic effect (4) Despite little scientific support, lasers have been employed for various indications including musculoskeletal disorders (e.g., carpal tunnel syndrome and lateral epicondylitis), pain relief, and wound healing. (7)

### **Muscular Skeletal Healing**

The Orthopaedic Section of the American Physical Therapy Association (APTA) published clinical practice guidelines for Achilles pain, stiffness, and muscle power deficits (11). The guidelines note that based on limited works, the future of LLL is promising for patients suffering from Achilles tendon pain. Given the limited number of studies employing LLL in this population, additional study is warranted. Clinicians should consider the use of low-level laser therapy to decrease pain and stiffness in patients with Achilles tendinopathy.

### **Pain reduction**

Zang et al (9) showed that LLL revealed promise in dealing with small fibre neuropathy in the foot However, in an evidence-based guideline for the treatment of painful diabetic neuropathy

published by American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation (10). The guideline notes LLLT is probably not effective for the treatment of this condition and is not recommended.

### **Onychomycosis**

Gupta (12) stated Laser therapy has been tested and approved as a cosmetic treatment only for onychomycosis. It cannot be recommended as a therapeutic intervention to eradicate fungal infection at this time as more rigorous randomized, controlled trials are required to determine if laser therapy is efficacious on par with oral and topical interventions.

### **Wound Healing**

There are several systematic technical reviews published regarding the use of low level laser for wound healing. The Agency for Healthcare Research and Quality (AHRQ) published a review of the comparative effectiveness and harms of different therapies and approaches to treating pressure ulcers. (13). Regarding low level laser therapy, the review found low strength of evidence for laser therapy and that wound improvement was similar with laser therapy compared with sham treatment or standard care. Low level laser therapy on wound areas as well as on acupuncture points, as a non-invasive, pain-free method with minor side effects, has been considered as a possible treatment option for the diabetic foot syndrome. The authors concluded that all studies gave enough evidence to continue research on laser therapy for diabetic ulcers, but clinical trials using human models do not provide sufficient evidence to establish the usefulness of LLLT as an effective tool in wound care regimes at present. They stated that further well designed studies are needed to determine the true value of LLLT in routine wound care.

### **Regulated Health Professions Act, 1991 (RHPA)**

In s, 27(2) of the Regulated Health Professions Act, 1991, S.O. 1991, c. 18, (RHPA) there are 13 controlled acts listed including: “applying or ordering the application of a form of energy prescribed by the regulations under this Act.”

Regulation 107/96 under this Act specifies the forms of energy prescribed for the purpose of paragraph 7 of subsection 7(2) as follows:

1. Electricity for,
  - i. aversive conditioning,



- ii. cardiac pacemaker therapy,
  - iii. cardioversion,
  - iv. defibrillation,
  - v. electrocoagulation,
  - vi. electroconvulsive shock therapy,
  - vii. electromyography,
  - viii. fulguration,
  - ix. nerve conduction studies, or
  - x. transcutaneous cardiac pacing.
2. Electromagnetism for magnetic resonance imaging.
3. Soundwaves for,
- i. diagnostic ultrasound, or
  - ii. lithotripsy.

A registered member of the College of Chiropodists of Ontario is exempt from subsection 27 (1) of the Act for the purpose of applying electricity for electrocoagulation or fulguration. O. Reg. 107/96, s. 2.

The forms of energy mentioned by name in the RHPA include electricity, electromagnetism and soundwaves. The legislation does not refer to laser therapy; therefore, the administration of laser therapy is not restricted and a nurse can administer it to clients.

This list is inclusive of all forms of energy that fall under the controlled acts in section 27(1) of the RHPA related to applying or ordering the application of a form of energy. There are many different forms of energy that are not listed as controlled acts in the RHPA. In instances where a specific form of energy is not listed in the legislation, the RHPA does not restrict how or by whom that form of energy may be applied. If an intervention or test is not listed in this Regulation, then it is not considered a form of energy according to the Regulation, and therefore not considered a controlled act. (14)

The College of Nurses of Ontario and The College of Kinesiologists of Ontario state that the use of Low Level Laser Therapy (LLLT is not a controlled act, and falls within the scope of its members. (14, 15)

### **Federal and Provincial Regulation of Lasers in Health Care**

Health Canada monitors the sale, importation and labelling of lasers, while the province of Ontario directs the local public health units to ensure the equipment is sanitary and will not spread infectious disease. Health Canada regulates laser devices to ensure that systems sold in Canada are “safe and effective when used for their licensed medical purposes by trained professionals according to the manufacturers’ directions” (16)

Lasers in Canada do fall under a variety of standards, these standards are directed at Occupational Health and Safety of practitioners and patients, not the clinical use of lasers CSA Z386-2014 *Safe use of lasers in health*, and ANSI Z136.3-2011 *Safe use of lasers in health care*.

Since 2002, the U.S. Food and Drug Administration (FDA) granted 510(k) approval to several companies to market lasers that provide LLLT. The LLLT lasers are classified as class II devices under the physical medicine devices section as “Lamp, non-heating, for adjunctive use in pain therapy.”

Bargman (17) indicated that no regulations existed in Ontario, that restrict the use of any Class 4 lasers. They are being used by lay people with no training or background in medicine. Galt (18) also noted that nobody regulates the actual use of these lasers, powerful devices that emit high-intensity light. They are used in doctor’s offices, clinics, salons and spas by individuals with a variety of professional backgrounds, including physicians, nurses and aestheticians.

In response, the College of Physician and Surgeons of BC have implemented accreditation standards that ensure Physicians are following safety guidelines when using Lasers

The Ontario Ministry of Labour (20) notes that hand-held Class 4 lasers are very rarely found in industry. Whilst in medical and veterinary practices, cosmetic treatment centres (skin care, hair and tattoo removal) and for some holistic uses, Class 4 devices are routinely hand-held. In Ontario, in addition to ANSI Standard Z136.1, CSA Standard Z386-14 – Safe use of lasers in health care facilities is referred to for medical applications. This standard is based on the ANSI Z136.3 and ANSI Standard Z136.1 standard`s.

The British Columbia’s Guideline for the safe use of lasers in veterinary practices is referenced as a guideline –that may be used by employers in the development of workplace training and by LSOs when drafting written standard operating procedures.

It was noted by the Technical Committee that this was the second referral by the Registrar related directly to the use of Lasers by registered member of the College of Chiropractors of Ontario. In light of this it was thought that the Executive and Council should consider

proactively developing Guidelines for use of Lasers by its members. In turn this should clarify other issues around Laser use, help protect the public and members by promoting safe and appropriate use of lasers. In the light of lack of other guidelines for use of Lasers by other regulatory Colleges in Ontario, including the College of Physicians and Surgeons of Ontario, it would demonstrate a leading role for COCOO in this area.

### **Conclusion**

The term cold laser therapy is used interchangeably with bio-stimulation, photo-biomodulation and Low Level Laser Therapy (LLLT). Cold laser therapy for the purpose of this submission is defined as ‘the use of red-beam or near-infrared lasers with a wave-length between 600 and 1000nm, power from 5–500 milliwatts’. The power densities used are lower than those needed to produce heating of tissue. Cold laser therapy is used for three main purposes: to promote wound healing, tissue repair, and the prevention of tissue death; to relieve inflammation and oedema because of injuries or chronic diseases; and as an analgesic and a treatment for other neurological problems. These applications appear in a wide range of clinical settings, ranging from dentistry, dermatology, rheumatology and physiotherapy

The Regulation under the RHPA refers to controlled acts and identifies the forms of energy that are prescribed. This list is inclusive of all forms of energy that fall under the controlled acts related to applying or ordering the application of a form of energy. If an intervention or test is not listed in this Regulation, then it is not considered a form of energy according to the Regulation, and therefore not considered a controlled act. (14) A registered member of the College of Chiropractors of Ontario is exempt from subsection 27 (1) of the Act for the purpose of applying electricity for electrocoagulation or fulguration. O. Reg. 107/96, s. 2. (No differences related to the application of energy are present between podiatrist and chiropractor class of members)

The legislation does not refer to laser therapy; therefore, the administration of laser therapy is not restricted and a member can administer it to clients. It is important to remember that controlled acts are not the only procedures that could potentially cause harm, and that having the authority to perform an activity does not necessarily mean it is appropriate to do so. Registered members of this College who perform–laser therapy should be aware that all practice standards would apply just as they would with any other procedure. When performing a procedure of any kind, registered members of the College must ensure they have the required knowledge, skill and judgment to perform the procedure safely and ethically, as well as manage outcomes.

The lack of Federal and Provincial controls over the use of Lasers of all classes has led to confusion and lack of clarity amongst members and the public alike regarding their use within the field of healthcare. Two referrals to the Technical committee about lasers highlight this issue. Disquiet within the physician community about lack of regulation is evident by recent articles and the development of accreditation standards in other provinces. The Executive and Council should proactively consider the production of Guidelines to members about the safe use of lasers by its members.

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