Low Level Laser Therapy Position Paper for the CMTBC: An Examination of the Safety, Effectiveness and Usage of Low Level Laser Therapy for the Treatment of Musculoskeletal Conditions

INTRODUCTION

The purpose of this position paper is to provide the Scope of Practice (SOP) Committee of the College of Massage Therapists of BC with current information about the safety, effectiveness and usage of Low Level Laser Therapy (LLLT) for the treatment of musculoskeletal conditions

in order for the SOP Advisory Panel to be adequately prepared to address the scope of practice of RMTs in relationship to laser therapy as well as light therapy and therapeutic ultrasound.

The BC Massage Therapy Regulation limits the scope of practice of massage therapy through specific prohibition of the use of "medical electricity", especially "hazardous" forms of energy which the Council states includes (therapeutic) ultrasound, electricity (TENS) and laser (LLLT). However, research studies over and over again report that LLLT is safe with no side effects and thus could be considered "non-hazardous". Among the many LLLT benefits relevant to massage therapists are a reduction in pain and an increased rate of healing.

In the past, clinical trials looking at the effectiveness of LLLT have often been poorly designed and any benefits seen have been discounted in systematic reviews. However, recently published studies indicate that LLLT is quite effective for a number of musculoskeletal conditions. Furthermore, two Cochrane systematic reviews that initially discounted the effectiveness of LLLT because of poor study designs have been withdrawn in light of the new evidence.

Finally, the use of LLLT is within the scope of practice of a number of regulated professional groups including Physiotherapists, Athletic Therapists, Naturopaths, Chiropractors, Acupuncturists, Medical Doctors, Dentists, Veterinarians and Estheticians, but not Massage Therapists. Also, Registered Massage Therapists in Ontario are permitted to use LLLT in their practice. More interestingly though is the fact that **anyone** can purchase a low level laser for the treatment of musculoskeletal conditions and use it without the supervision of a trained professional.

Because LLLT is a safe and effective method of enhancing the healing process and reducing pain, it is easy to see why RMTs would want to incorporate its use into their practice.

WHAT IS LOW LEVEL LASER THERAPY?

Low Level Laser Therapy (LLLT) is also known as Low Intensity Light Therapy (LILT), cold laser, phototherapy, light therapy, low-energy laser therapy, photobiomodulation among other

terms (Meditech/BioFlex). Laser is an acronym for "**L**ight **A**mplification by **S**timulated **E**mission of **R**adiation".

The radiation referred to is electromagnetic radiation which travels in waves of photons and different types of electromagnetic radiation possess different wavelengths and thus different intensities. Electromagnetic radiation includes everything from very short, ionizing gamma rays (given off by nuclear weapons), x-rays, ultraviolet rays, as well as non-ionizing visible light, infrared waves (heat), and very long radio waves. Ionizing radiation damages cells through the breakage of bonds, while non-ionizing radiation does not. High intensity wavelengths generate heat.

Lasers produce a small, concentrated, monochromatic (one wavelength) beam of electromagnetic energy which concentrates the wavelengths in one area. The range of wavelengths of electromagnetic radiation varies between types of lasers and spans the spectrum of visible light and includes infrared light as well (Robertson, 2006). Different manufacturers claim that their products give off more effective wavelengths that others and they often patent their wavelength.

Laser radiation can be absorbed, reflected and refracted just like any type electromagnetic radiation including visible light. The monochromatic beam passes unaltered through air, but when it hits liquid the electromagnetic radiation it is altered. For example, when it hits tissue the radiation can be absorbed by the cells (Robertson 2006).

Characteristics of Low Level Lasers

Typically, lasers used for therapeutic purposes fall in the red and near-infrared ranges of electromagnetic radiation and thus in the non-ionizing range. The wavelength range for red light is 630 - 700 nm and the range for near-infrared radiation is 700 nm to 1 mm. Therapeutic lasers use these wavelengths because other wavelengths are absorbed by melanin pigment in skin, hemoglobin in blood or water in the tissues and thus don't reach the mitochondria of the targeted tissues. In addition, studies have shown that wavelengths in the red through near-infrared spectrum (630-900 nm) are best absorbed by the iron or copper atoms associated with the cytochrome system in mitochondria for ATP production (more about this later) (Meditech Physics Presentation DVD).

With true lasers, the intensity of the light remains consistent even when the source of the beam is moved away from the target; a characteristic called coherence. The wavelengths of light from light emitting diodes, or LED lasers, spread out in all directions when pulled away from the target (non-coherent) and are thus thought to not penetrate tissue as well. However, these types of "cold lasers" do not give off heat and can be held directly against the skin. More powerful lasers can give off heat; even enough heat to cut tissue and damage the retina.

Laser Classification (US FDA)

Lasers are classified based on these different properties (coherence of the beam, depth of penetration, wavelength) as well as their power, duration of the "on time" when pulsed, and their effect on the eye.

- Class 1 lasers (for example barcode readers and some types of LED or super-luminous diode therapeutic lasers) do not affect tissues, have the lowest power rating and eye protection is not required for their use.
- Class 4 and 5 lasers at the other end of the laser spectrum are surgical lasers that cut tissue. They are very high powered and must be used under extreme precautions.
- Laser pointers for classroom use are usually class 2 or 3A lasers with a relatively low power rating, but can cause temporary visual disturbance when pointed at eyes.
- Some therapeutic lasers are classified class 3B and as mentioned with laser pointers, the beam could affect the eyes and protective eyewear should be worn. The class 3 infrared wavelengths A and B refer to near infrared or short wavelengths (A) and far infrared or long wavelengths (B). Class 1, 2 and 3(A and B) lasers do not harm tissue (Robertson, 2006). They are also considered the best balance of power output (less than 500mW) and safety (ChiroEco, 2005).

Thus, therapeutic lasers that fall into **class 1 do not harm tissue and do not affect the eyes**. The document covering the use of lasers for laser hair removal states that "class 1 lasers cannot emit harmful accessible radiation levels and are exempt from all control measures" (Laser Hair Removal Guidelines).

Therapeutic lasers that fall into class **3B do not harm tissue, but protective eyewear is necessary for the therapist and the client**. Some companies (Meditech/BioFlex) have built in safe-guards to prevent the class 3B laser probes from turning on unless they are pressed right on the skin surface.

There are two types of therapeutic lasers typically used for the treatment of musculoskeletal conditions. The first type are helium-neon lamps that give off a visible red light with a wavelength range of about 630-700 nm. The second type of therapeutic laser is the light emitting diode (LED) laser which is a semi-conductor laser made from gallium and aluminum arsenide (GaAlAs). They give off electromagnetic radiation wavelengths that range from 630nm (red light) to 1550nm (infrared light or heat). Sometimes several smaller laser diodes are grouped together to form larger emitters or cluster probes to treat larger areas of the body (Robertson, 2006). When the wavelengths are in the near-infrared range (700 nm-1 mm), the laser is considered at class 3B laser device. A company's LLLT device may contain these two separate types of lasers utilizing the red light and near-infrared light benefits.

Other relevant features of therapeutic lasers that relate to safety are their power (rate at which energy is produced and range from 250-1500W), their output power (related to the class of laser with class 1 having the lowest) wavelength of light beam, and pulse lengths. Note that the **input power** entering the device, is not indicative of the output power. The output power is in the milliwatt (mW) range while the input is 1000 times greater and of course could cause damage.

It is important to note that with higher **power outputs** (that could cause tissue damage) the beneficial effects are lost. More power does not mean faster healing. Thus most therapeutic lasers have a power output of 500 mW (those for home use are usually much lower). Because the power output is relatively low at 500 mW or less, therapeutic lasers are also known as cold lasers because they do not give off enough thermal energy to heat up the tissue being treated. (Q Laser). The Mediflex/Biotech laser diode has a output power of 180 mW and the superluminous LED has a power of 8.5 mW (Meditech physics presentation), definitely falling into the cold laser category.

Wavelengths likely to penetrate tissues deeper than the skin range from 650 nm to 1500 nm (Robertson 2006). For example, BioFlex uses 660nm, 830 nm and 840nm to maximize the absorption of light by different molecules. The red light wavelengths (660 nm) are more likely to be absorbed by other molecules and thus do not penetrate deeply versus the near-infrared wavelengths of 830 and 840 nm (Meditech/Bioflex Presentation). This 830 nm wavelength seems to be used by a number of different products (Meditech, MicrolightLaser) however one

company, Theralase, has a laser with a 905 nm wavelength that gives a 4 inch depth of penetration (http://www.theralase.com/brochures/tlc%201000%20-%20sell%20sheet%20--web.pdf).

Low level lasers are thought to promote healing and reduce pain possibly through the reduction of inflammation. Healing may come about by increased cell proliferation. Gao et al. (2009) reviewed the LLLT literature to look at the effects on tissues (human and other systems) at the cellular level. They found evidence supporting laser-induced proliferation of different cell types such as fibroblasts, muscle cells, osteoblasts and keratinocytes (skin cells) and came up with a mechanism of action. "Low power laser irradiation (LPLI) promotes proliferation of multiple cells, which (especially red and near infrared light) is mainly through the activation of mitochondrial respiratory chain and the initiation of cellular signalling". **Dosage is also very important; too much and the effect is lost.**

Classifications of Some Lasers Sold in Canada

Class 1 laser diodes sold in Canada that should be deemed safe and effective.

- Meditech/BioFlex lasers: first two stages of treatment (http://practitioners.meditech-bioflex.com/laser-therapy/choosing-a-laser-therapy-system.php)
- Q1000: http://www.21stcenturyhealing.com/coldlasertherapy/safety.html)

Class 3B (that may harm the eyes)

- Meditech/BioFlex lasers: (http://practitioners.meditech-bioflex.com/laser-therapy/choosing-a-laser-therapy-system.php) third stage of treatment
- Theralase: TLC-1000 (http://www.theralase.com/brochures/tlc%201000%20-%20sell%20sheet%20--web.pdf)
- PainThor Photomedicine system (http://www.painthor.com/the-package.html)
- Terraquant (http://www.terraquant.org/)

LASER SAFETY

Approval of Lasers

Any laser sold in Canada must be approved by Health Canada. This information is usually included on the laser manufacturer's website such as for the BioFlex Laser sold by Meditech The Meditech website states that "Meditech manufactures BioFlex Systems under the ISO 13435 quality system, which meets the requirements of Health Canada, the FDA and the EEU (CE Mark)" and that "Meditech holds permission to market BioFlex Systems in Canada under a

Canadian Device Licence" (http://patients.meditech-bioflex.com/equipment/bioflex-home-laser-therapy-equipment.php). Theralase even includes their Health Canada Certificate on their website (http://www.theralase.com/certificates/healthcanadacertificate.pdf). Their model, the TLC-1000, is a class 3B laser diode. The US FDA's guidelines for laser devices distributed for human (and animal) treatment state that lasers must meet Mandatory Performance Standards which include "safety features and labelling to provide adequate safety to users and patients". Thus, FDA certification of the laser devises means that it has "passed a quality assurance test and that it complies with the performance standard" (FDA Laser Information, 2009).

Many jurisdictions (PEI, Saskatchewan) do not regulate LLLT and this means that individuals other than regulated practitioners can purchase and use lasers for the purpose of laser therapy. The Health Professions Act of Alberta does not include laser therapy as a restricted modality and this has been interpreted to mean that individuals other than regulated practitioners can use them (FAQ on Lasers Alberta).

The Ontario Act even explicitly permits Massage Therapists to use low intensity laser therapy (http://www.cmto.com/regulations/ModComplementSecA.htm).

The US FDA points out that individual states regulate who can use lasers for various therapeutic procedures. Medical lasers are prescription devices available for sale only to licensed practitioners. They recommend that these individuals check with their state medical licensing board to determine who qualifies as a licensed practitioner in your state (FDA Laser Information).

One thing to note, therapeutic lasers are typically approved by Health Canada and the US FDA for the treatment of very specific conditions such as carpal tunnel pain not pain in general. Thus a laser that has received approval, has usually done so for the treatment of usually one condition. For example, the first laser approved by the FDA for **home use** is the Q1000 specifically to treat osteoarthritis, of the hand (ChiroEco, 2009). This is a Class I laser device and the FDA approved it because there is no risk of harm to the eyes.

Safety of the Equipment

Concerns about the dosage of lasers have been addressed by the various manufacturers. In the past, researchers have reported that lasers did not perform as expected, but the problem was that they underperformed. In one 1999 study, 60% of laser diodes and 31% of superluminous diodes were within 1 to 79% of the expected levels of power – an unacceptable range (Robertson 2006).

Improvements have been made to maintain consistent output. The Meditech/BioFlex website states that "the BioFlex system has both an internal feedback loop that directly measures the quantity of light being emitted and a feedback loop that measures the current within the device to ensure proper dosage" (http://practitioners.meditech-bioflex.com/laser-therapy/choosing-a-laser-therapy-system.php). Also with the Meditech/BioFlex class 3B laser probe that is used in the last stage of treatment, the beam can only be engaged when the tip of the probe is pressed against the tissue (personal communication Milley).

Calibration of Equipment

Calibration and monitoring of the equipment is required by Health Canada and the US FDA. Meditech recommends that the equipment be shipped back to every 20-22 months for a calibration check and adjustment if necessary at a cost of $100 per system plus shipping (Bryan Milley, personal communication). There are also private laser safety companies that can test equipment shipped into them (http://www.laserproductsafety.com/)

Training of Laser Therapists

Health Canada requires that everyone operating a laser device be properly trained. The Matrix Institute for Laser Therapy provides laser therapy training to healthcare professionals who are **licensed** in their field: Medical Doctors, Psychologists, Chiropractors, Dentists, Nurses, Naturopathic Doctors, Oriental Medicine Doctors, Dieticians/Nutritionists, Physiotherapists Acupuncturists, Reflexologists, Medical Technologist or Clinical Laboratory Scientist, Medical Assistants, **Massage Therapists**, Sports Medicine, Estheticians/Cosmetologists. They do note however that "it is the sole responsibility of the students practicing Laser Therapy to comply with Federal and State laws" (http://www.matrixths.com/whocantrain.aspx). With Meditech/BioFlex lasers, training is required for each clinic operating a laser system. They provide certification for those operating their laser devices once they have completed the training

(Bryan Milley, personal communication). This company seems to be the most aggressive at marketing in Canada and has offered training courses in BC for various professionals. The Theralase website includes good training videos (http://www.theralase.com/sub.php?lasertherapy=15) .

Note that in BC, some Registered Massage Therapists are advertising that they are also Certified Laser Therapists and other RMTs are advising their clients/patients on the best use of their home lasers for the treatment of conditions.

The Question of Cosmetologists/Estheticians

At a minimum, class 1 lasers have been approved for home use, so anyone can buy them. But who else can use lasers? As noted above, a number of regulated health care professionals with many years of college or university training can use lasers as a part of their scope of practice. But so can cosmetologists and estheticians in British Columbia and they have significantly less education than any of these professionals as well as registered massage therapists . An example of the requirements to become a licensed cosmetologist in BC would be the Northern Lights College. It has a 10 month program and the entry requirement is 67% or higher in Grade 10 English, Math and Science (Northern Lights). They can then write the Cosmetology Industry Association of British Columbia Certificate of Qualification exam and then be eligible to take a LLLT certification course and not only use LLLT themselves, but oversee unlicensed, uncertified staff who use the equipment. They are deemed safe with only 10 months of school and without necessarily graduating from high school. (Note that the entry requirements for massage therapy colleges in BC require high Grade 12 graduation with English 12 and Biology 11 and/or 12 is highly recommended. The programs are approximately 3000 hours (Okanagan College). Also note that the BC Government deregulated the Cosmetology Act as of December 31, 2003 (http://www.ciabc.net/exams.html).

Cosmetologists or estheticians use class 3B lasers (and even class 4) for laser hair removal or tattoo removal. Class 4 labels can damage the skin and are considered hazardous.

There are a variety of laser systems on the market that have a number of different applications. Lasers purchased by estheticians also have other capabilities such as pain management: Harmony Laser system by Alma (http://www.almalasers.com/harmony_xl.jsp) , Q1000 laser (http://www.stumblingglass.com/hygiene-health/article3027.htm) , Theralase (http://www.theralase.com/brochures/tlc%201000%20-%20sell%20sheet%20--web.pdf) all of which have the capability of modifying the wavelength and power output to treat pain and inflammation. This is even clearly stated on their websites. All an esthetician has to do is order the appropriate probe and change the setting and then they can treat patients with knee pain. (Note that I have received anecdotal accounts of this practice told to me in confidence!)

Contraindications

Although the literature doesn't mention any adverse effects, some websites associated with the sales of therapeutic lasers or sites for laser therapy do mention some possible side-effects. The Canadian Laser Therapy's website indicates that "there are two basic contraindications: patients on photoactive medication and women in their first trimester of pregnancy" (Canadian Laser Therapy). Meditech/BioFlex also lists tattoo surfaces as a contraindication as the pigments in the tattoo could absorb heat and possibly lead to burning of the skin. They also recommend setting changes darker skin tones (Meditech/Bioflex).

MicrolightLaser® therapeutic laser system website also refers to other possible contraindications. Here is the excerpt:

1. PACEMAKERS – While some have suggested caution in using LLLT in the presence of pacemakers, no evidence has been presented. Because LLLT uses light, no influence on the pacemaker results from its use.
2. EPILEPSY – Pulsed visible light can have an effect on certain individuals susceptible to this condition, however, invisible, non-pulsed laser light (as is provided by the ML-830) has had no reported detrimental effect on seizure-susceptible patients.
3. DIABETICS – While this has been suggested as a contraindication, no evidence has been found to show that LLLT could aggravate symptoms. In fact several studies have shown dramatic improvement in healing of wounds of diabetics with LLLT.
4. CHILDREN – The concerns originally expressed for use of LLLT near growth plates in children have been found to be unwarranted. No detrimental bone growth effect has been documented, and in fact, LLLT in children has been found to be beneficial in pediatric fractures. (http://www.westwood-clinic.com/LaserTherapy.html):

Laser Light Therapy Canada's website gives a list of contraindications for the use of their Diobeam 830 model (http://www.laserlightcanada.com/).

Do not treat:

- Directly into eyes (retinal exposure to Class 3B laser may cause eye damage)
- Over a pregnant uterus
- Over any suspicious lesion or cancer
- Over thyroid gland
- Over an area injected with steroids or other anti-inflammatory medication in previous week
- Someone hypersensitive to light in the 830nm wavelength region
- Patients with seizure disorders triggered by light
- Patients taking medications for which sunlight exposure is a contraindication
- Over open wounds or herpes simplex unless unit covered with a clear protective barrier

Finally, the Chiropractic Clinical Guidelines for evidence-based treatment of adult neck pain not due to whiplash mentioned risk factors that are absolute contraindications to cervical low-level laser therapy: "Cardiovascular disease, hypertension, coagulopathy, ulcer, recent severe hemorrhage, renal insufficiency, severe hepatic disease, neoplasia, epilepsy, cutaneous pathology, pain of "central" origin, pregnancy" (Peacock et. al. 2005).

Low Level Laser Therapy Safety Literature

I didn't find a single published study that reported adverse effects associated with the use of any of the classes of therapeutic laser. Here is a sampling of the many papers that reported no side effects to LLLT. Yousefi-Nooraie et al. (2007) in their Cochrane Review of LLLT for **nonspecific low-back pain** reported that none of the seven studies with a total of 384 people reported any side-effects with the use of low level lasers. Similarly, the Brosseau et al. (2005) Cochrane review of the effects of laser therapy for **rheumatoid arthritis** reported no side in the 5 placebo-controlled trials they examined (222 subjects, 130 of which received laser therapy). In a RCT by Dundar et al. (2007) to study the effect of the GaAsAl low level laser on **myofascial pain syndrome**, laser therapy was found to be no more effective than the placebo but the authors indicated that no side-effects were observed! Gur et al (2002) also reported no side effects in their randomized, single-blind, placebo-controlled study to examine the effectiveness of LLLT for **fibromyalgia**. The study included 40 subjects and a Ga-As laser was used.

LASER EVIDENCE FOR EFFECTIVENESS

Comments on Past Criticism of the Literature

Prior to mid-2008, the evidence to support the use of LLLT for tissue healing (such as muscle tears, hematomas, tendinopathies) and pain control has been questionable. Three LLLT Cochrane Reviews, one for the treatment of low back pain (Yousefi-Nooraie et al. 2008), one for the treatment of rheumatoid arthritis (Brosseau et al. 2005) and one for the treatment of osteoarthritis (Brosseau et al. 2007) concluded that the methodologies of most of the randomized, controlled clinical trials were poorly designed. However, in recent months two of these reviews have been withdrawn. In the case of Brosseau's 2007 review of LLLT for osteoarthritis there were two reasons for withdrawal including "comments received have suggested the presence of a substantial number of additional trials claiming positive results that need to be reviewed, and that, if eligible, could affect the (previously unfavorable) conclusions." One of these studies by Hegedűs et al. (2009) just came out in the last month.

It was also concluded by Brosseau et al. (2005) that:

> "Clinicians and researchers should consistently report the characteristics of the LLLT device and the application techniques used. New trials on LLLT should make use of standardized, validated outcomes. Despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage and site of application over nerves instead of joints."

Cochrane systematic reviews and other systematic reviews are often the basis for the decisions of medical insurance companies to provide coverage for a treatment. But what if these systematic reviews are invalid? Bjordal et al (2005) criticized the Cochrane review process in regards to their systematic review of LLLT for the treatment of rheumatoid arthritis. Note that Bjordal was lead author in a systematic review of LLLT for elbow tendinopathies – not a Cochrane Review (Bjordal et al. 2008) and thus has some experience in the area. Bjordal et al. looked at the validity of this Cochrane review by testing it against a nine-item checklist for systematic reviews. One of the key findings was that the review group only included clinicians who had previously performed LLLT trials that failed to find any benefits of LLLT. The review group also included data from questionable studies which produced results that "systematically favored the negative review conclusion". It was concluded that the rheumatoid arthritis Cochrane review was not

valid and Bjordal et al. suggested that in the future there should be "representation of experts and different views on efficacy in the review group and extensive use of sensitivity analyses could probably improve quality control of reviews in areas of controversy".

Based on these negative Cochrane reviews, medical insurance companies refused to reimburse for low level laser therapy. Cigna's latest Medical Coverage Policy (Cigna 2009) document states:

> "Low-level laser therapy (LLLT) has been proposed for a wide variety of uses, including wound healing, tuberculosis, and musculoskeletal conditions such as osteoarthritis, rheumatoid arthritis, fibromyalgia and carpal tunnel syndrome. **There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that LLLT is effective for these conditions** or other medical conditions. Large, well-designed clinical trials are needed to demonstrate the effectiveness of LLLT for the proposed conditions." (Cigna 2009)

Although the Cigna policy included a fairly extensive reference list, their reference for the Cochrane Review on LLLT for osteoarthritis was dated 2005 suggesting they were unaware of the 2007 update or the withdrawal of that 2007 review (which incidentally was available on PubMed prior to the July 15, 2009 effective date of the policy).

Critics of LLLT research studies, especially medical insurance companies that require a huge burden of proof before they will cover something new, will focus on a phrase commonly included at the end of RCTs; the authors often recommend that more research is needed, especially trials with larger sample sizes. This is common practice in all health science research especially if the clinical trial in question was the first to be carried out for a particular treatment or condition. The goal is to ensure external validity by having other independent researchers attempt to repeat the study and hopefully achieve the same outcomes. Additionally, when future researchers (including the authors of the original study) want to perform another study in the same general area, it supports their funding application to reference past studies that recommend further research be done.

Examples of Conditions that Benefit from LLLT

Among the many benefits associated with LLLT are a reduction in pain and an increase in range of motion (osteoarthritis, TMJ, myofascial pain syndrome of the neck), an increased rate of healing for a number of tendinopathies including Achilles tendinosis/itis and lateral epicondylitis, reduce lymphedema post mastectomy, decreased symptoms of carpal tunnel syndrome (paresthesia and numbness) with increased grip strength and finally reduced creatine kinase levels with pre-treatment before vigorous exercise.

Carpal Tunnel Syndrome

In a review of 7 laser therapy clinical trials using photoradiation to treat carpal tunnel syndrome (CTS) Naeser (2006) reported that the 5 studies that demonstrated low level laser therapy was effective at reducing pain used a higher power than the 2 that did not show a benefit over the control group. A more recent, better designed study involving 80 subjects and a sham laser control group concluded that LLLT reduced the carpal tunnel syndrome symptoms of paresthesia and numbness as well as improved hand grip and electrophysiological parameters (Shooshtari, 2008). Evick (2007) found that LLLT over the carpal tunnel area improved hand and pinch grip strength and Chang (2008) concluded that the same thing plus that LLLT alleviated carpal tunnel syndrome pain and symptoms.

Fibromyalgia

A single-blind, RCT with 40 female subjects was conducted to see if LLLT could reduce the symptoms of fibromalgia (Gur et al. 2005). Those in the control group received placebo laser while the treatment group received a Ga-As laser treatment daily for two weeks (excluding weekends). The author's concluded that laser therapy was a safe and effective way to relieving pain, muscle spasm, morning stiffness, and total tender point number associated with fibromyalgia.

Frozen Shoulder

A preliminary RCT with 63 subjects examined the effects of LLLT on frozen shoulder. The control group received placebo laser and the active laser group was treated with a 810-nm Ga-Al-As laser with a continuous output. The author determined that there was a significant

decrease in pain and disability in the treatment group versus the placebo control group (Stergioulas 2008).

Lymphedema - Postmastectomy

Kozanoglu et al. (2009) reported positive effects with low level laser therapy for the reduction of limb size and pain with of patients with postmastectomy lymphedema. Also the benefits of LLLT lasted longer than pneumatic compression, the usual treatment and the control in this study.

Myofascial Pain Syndrome

Low level laser therapy has also been used to treat myofascial pain syndrome of the neck (Gur et al. 2004). In this double-blind RCT with 60 subjects, treatment with a Ga-Ar laser (904 nm) resulted in reduced pain, improved function and improved quality of life as compared with the placebo laser control group.

Osteoarthritis

In response to Brosseau et al.'s (2007) Cochrane Review (discussed earlier) that criticized the methodology of past low level laser therapy studies on the effects of osteoarthritis, Hegedűs et al. (2009) performed a double-blind, RCT which was just published this June. They concluded that LLLT for osteoarthritis of the knee reduces pain and increases microcirculation in the treated area. Also a systematic review of the literature by Jamtvedt (2008) examined various physiotherapy interventions for osteoarthritis of the knee and noted that there was high quality evidence that exercise and losing weight can reduce pain, but that there was also moderate-quality evidence that low-level laser therapy can do so as well (along with TENS and acupuncture).

Pain

In a review of 22 RCT involving the biological and clinical effects of photoradiation (LLLT) in acute pain to due soft tissue injury Bjordal et al. (2006) reported that in 19 of 22 studies that photoradiation reduced inflammatory pain in the subjects. They looked at a variety of biochemical markers, neutrophil numbers, formation of edema and hemorrhage. They

commented that adequate dosage was important to see an effect. In a small study by Junior et al. (2009) eight subjects received pretreatment of the rectus femoris muscle by an LED multi-diode or cluster laser before undergoing high-intensity exercise. They found that the subjects had significantly lower levels of post-exercise creatine kinase (CK) compared to the placebo cluster group and the active single-diode laser group. However, other outcome measures were not affected (Wingate tests and post-exercise blood lactate). In a systematic review of non-invasive therapies for neck pain, Hurwitz et al. (2008) stated that for neck pain other than whiplash, the evidence suggests that low-level laser therapy was more effective than no treatment or sham treatment. In a study of general knee pain, Montes-Molina et al. (2009) reported that interferential laser therapy (using two identical laser probes located opposite each other on the knee joint) was no better than the conventional method of just one laser probe over the affected area.

Rheumatoid Arthritis

Brosseau et al.'s (2005) Cochrane Review of the effects of LLLT for rheumatoid arthritis, reported that it reduced pain and morning stiffness with a minimum four-week treatment program, but other clinical findings were inconsistent. Yamaura et al. (2009) investigated the mechanism behind how LLLT reduced joint pain in rheumatoid arthritis. They concluded that it may involve "reducing the level of pro-inflammatory cytokines/chemokines produced by synoviocytes. This mechanism may be more general and underlie the beneficial effects of LLLT on other inflammatory conditions".

Temporal Mandibular Joint Syndrome (TMJ)

Thirty-five subjects were assigned to either the treatment group receiving LLLT along with a daily exercise program or the placebo group which just followed the exercise program. Significant improvement in TMJ symptoms were obtained in the treatment group that received LLLT both in "subjective parameters such as pain and number of tender points, as well as in objective functional parameters such as mouth opening and lateral motions". The placebo group only experienced pain reduction (Kulekcioglu, 2003).

Tendinosis - Achilles Tendon

In an RCT of 52 recreational athletes with chronic Achilles tendinopathy, low-level laser therapy combined with an eccentric exercise regimen was shown to accelerate clinical recovery (reduce pain intensity during exercise post-treatment) compared to eccentric exercise (EE) alone. The results at 4 weeks were similar to the EE group lacking LLLT at 12 weeks (Stergiolas 2008).

Tendinosis - Lateral Epicondylitis

The authors of more recent publications have taken the advice of systematic reviewers into consideration and have used more rigorous methodology in their studies. A case in point is the recent evidence regarding the treatment of lateral epicondylitis (tennis elbow or lateral elbow tendinopathy) with LLLT. Past studies were weak leading to systematic reviews drawing the conclusion that laser therapy wasn't effective. However, recent findings by authors such as Shooshtari (2008) who's study involved 80 subjects and a sham laser control group concluded that LLLT reduced the carpal tunnel syndrome symptoms of paresthesia and numbness as well as improved hand grip and electrophysiological parameters. This had lead to the most recent systematic review by Bjordal et al (2008) concluding that LLLT "administered with optimal doses of 904 nm and possibly 632 nm wavelengths directly to the lateral elbow tendon insertions, seem to offer short-term pain relief and less disability in lateral elbow tendinopathy, both alone and in conjunction with an exercise regimen". The authors also state that "this finding contradicts the conclusions of previous reviews which failed to assess treatment procedures, wavelengths and optimal doses".

In a RCT comparing LLLT to bracing and ultrasound in the treatment of lateral epicondylitis, 68 subjects were divided into the 3 groups (with subjects in each group also performing exercises throughout the study). The authors concluded that laser therapy was more effective at reducing pain than the brace, had a longer lasting effect than the brace and was more effective at improving grip strength than the brace or ultrasound treatment.

Animal Study – Myofascial Trigger Points

In an animal study by Chen et al (2008) eight rabbits with one myofascial trigger point in each biceps femoris muscle were treated on one side with a gallium-aluminum-arsenate (GaAlAs) laser (six treatments with a wavelength of 660-nm, continuous-wave, at 9 J/cm2). The contralateral side received a sham laser "treatment". The end-plate noise recorded by the

electromyograph was significantly reduced on the laser treated side post-treatment. The author's concluded that "laser irradiation may inhibit the irritability of an myofascial trigger point in rabbit skeletal muscle. This effect may be a possible mechanism for myofascial pain relief with laser therapy."

CONCLUSIONS

Many of my findings correspond to those of found in George Bryce's *Hazardous Energy Reserved Act for Physical Therapists: Implications for Massage Therapists and other Health Professions*. I am at a loss to figure out why his comments were ignored back in 2003. One of the biggest issues was that the distinction wasn't made between the different types of lasers on the market and their risk of harm; there is clearly a difference between lasers that harm tissue and those that don't.

1. Low level lasers require electricity for function, but give off wavelengths of red light or infrared light. Thus they are not considered to conduct electricity into the body (unlike TENS machines).

2. Class 1 lasers do not harm the eyes. They also do not produce heat and thus do not harm tissue.

3. Although Class 3B lasers can harm the eyes (thus goggles are recommended), most brands (including Meditech/BioFlex) include safety precautions that prevent accidental exposure. Also, Class 3B laser devices are in the low output power range (below 500 mW) so do not give off heat. If they do not give off heat, they cannot damage tissue in the treatment area. (Note that highly focused class 3B lasers used by cosmetologist for laser hair removal can harm tissue.)

4. There are a number of possible contraindications to LLLT, especially class 3B lasers. A definitive list should be developed.

5. Low level lasers function by providing electromagnetic energy to energy systems within cells to increase cell proliferation and reduce inflammation. Many well designed RCTs support this effect by LLLT for the treatment of many musculoskeletal conditions as do animal studies. There is evidence to support the use of class 3B lasers in the treatment of tendinoses, knee pain, lymphedema post-mastectomy, rheumatoid arthritis, TMJ, osteoarthritis, fibromyalgia, and carpal tunnel syndrome. Most of these rigorous studies have been published just in the last year.

6. Cochrane systematic reviews have previously criticized LLLT research and thus claimed the evidence did not support its effectiveness in the treatment of osteoarthritis and low back pain. These two Cochrane reviews have recently been withdrawn in light of new evidence.

7. Critics of LLLT research studies will focus on the typical authors' statement at the end in the conclusion that recommends that further larger clinical trials should be carried out. This is common practice in all health science research especially if a clinical trial was the first in a particular research area. The goal is to ensure external validity by having other independent researchers attempt to repeat the study and hopefully achieve the same outcomes.

8. Low level lasers have been deemed safe and effective by Health Canada and the FDA and many models can be purchased by the general public for home use.

9. Cosmetologists in BC with much less education and training than Registered Massage Therapists can use even higher powered class 4 lasers for hair and tattoo removal. These lasers do harm tissue. The laser systems they can buy can also deliver the dosage for LLLT and who's to stop them from using them for this purpose.

10. Additionally, anyone can work under a certified laser therapist and treat clients as long as they follow safety guidelines in their facility. What is to stop a Registered Massage Therapist from taking the certification course and then hiring someone (without training of any type) to actually perform the laser therapy?

11. Through the use of class 3B lasers Registered Massage Therapists in BC would be able to provide additional benefits to their clients by increasing the rate of healing and reducing inflammation.

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