Clinical Policy Bulletin:
Cold Laser and High-Power Laser Therapies

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Policy

Aetna considers cold laser therapy (also known as low-level laser therapy or class III laser) and high-power laser therapy (class IV therapeutic laser) experimental and investigational for the following indications (not an all-inclusive list) because there is inadequate evidence of the effectiveness of cold laser therapy and high-power laser therapy for these indications:

- Bone regeneration
- Carpal tunnel syndrome
- Colorectal cancer
- Dental pain
- Dentin hypersensitivity
- Elbow disorders
- Fibromyalgia
- Herpes labialis
- Lymphedema
- Musculoskeletal dysfunction
- Myofascial pain syndrome
- Neurological dysfunctions,
- Pain relief (e.g. acute and chronic low back pain/neck pain, orthodontic pain, shoulder pain)
- Patella-femoral pain syndrome
- Physical therapy (including rehabilitation following carpal tunnel release)
- Rheumatoid arthritis
- Shoulder impingement syndrome
Temporomandibular joint disorders
Tinnitus
Wound healing (including diabetic ulcers and gingival healing)

See also CPB 0604 - Infrared Therapy.

**Background**

Low-energy lasers (also known as cold lasers or class III lasers) have been promoted as an effective way to produce analgesia and accelerate healing of a variety of clinical conditions.

By definition, low energy laser therapy uses 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/cm² and laser powers to 500 mW or less.

Despite these constraints, a wide variety of types of lasers, treatment schedules, and techniques have been used. Consequently, apparently conflicting results from studies of low-intensity lasers may not be in conflict, and may represent fundamental, but poorly understood, differences in treatment approaches.

Although the results from large, uncontrolled, open trials of low-energy lasers in inducing wound healing have shown benefit, controlled trials have shown little or no benefit. The analgesic effects of low-energy lasers have been most intensely studied in rheumatoid arthritis. Recent well-designed, controlled studies have found no benefit from low-energy lasers in relieving pain in rheumatoid arthritis or other musculoskeletal conditions. Furthermore, although positive effects were found in some earlier studies, it was not clear that the pain relief achieved was large enough to have either clinical significance or to replace conventional therapies.

Published systematic reviews of the evidence have concluded that there is a lack of adequate evidence of effectiveness of cold laser therapy for treatment of chronic wounds (e.g., Schneider and Hailey, 1999; Cullum and Petherick, 2007; Flemming and Cullum, 1999; Samson et al, 2004; Simon et al, 2004; Wang, 2004; Nelson and Jones, 2006), arthritis (Brosseau et al, 2007; Brosseau et al, 2005; Marks and de Palma, 1999; Puett and Griffin, 1994; Wang, 2004), tuberculosis (Vlassov et al, 2006; Ziganshina and Garner, 2005), tinnitus (Waddell, 2004), smoking cessation (White et al, 2006), epicondylitis (Chapell et al, 2002), Achilles tendinitis (McLauchlan et al, 2001), plantar heel pain (Crawford and Thomson, 2003; Landorf and Menz, 2007), back pain (Yousefi-Nooraie et al, 2008), and other musculoskeletal disorders (de Bie et al, 1998; Abdulwadud, 2001; Ohio BWC, 2004; Wang, 2004). Systematic evidence reviews have also concluded that low-energy laser therapy (e.g., Microlight 830, Microlight Corporation of America, Missouri City, TX) is ineffective in treating carpal tunnel syndrome (Gerritsen et al, 2002; O'Connor et al, 2003; Ohio BWC, 2004; Wang, 2004; CTAF, 2006).

A recent study (Hirschl et al, 2004) evaluated the effectiveness of low-level laser therapy in patients with primary Raynaud's phenomenon (n = 48). Laser and sham therapy each were applied 5 days a week for 3 weeks. The authors found that low-level laser therapy reduced the frequency and severity of Raynaud attacks. The
findings of this study were interesting but need to be validated by further investigation with more patients and follow-up.

Kreisler et al (2004) assessed the effect of low-level laser application on post-operative pain after endodontic surgery in a double-blind, randomized clinical study. A total of 52 healthy adults undergoing endodontic surgery were included into the study. After suturing, 26 patients had the operation site treated with an 809 nm-GaAlAs-laser at a power output of 50 mW and an irradiation time of 150 seconds. Laser treatment was simulated in another 26 patients. Patients were instructed to evaluate their post-operative pain on 7 days following surgery by means of a visual analogue scale. The results revealed that the pain level in the laser-treated group was lower than in the placebo group throughout the 7 day follow-up period. The differences, however, were significant only on the first post-operative day. The authors stated that low-level laser therapy can be beneficial for the reduction of post-operative pain. However, its clinical effectiveness and applicability with regard to endodontic surgery need further investigation, especially in terms of the optimal energy dosage and the number of laser treatments needed after surgery.

In a randomized controlled study, Bingol et al (2005) examined the effect of low-power gallium-arsenide laser treatment on the patients with shoulder pain. A total of 40 patients with shoulder pain and complied with the selection criteria were included in the study. They were randomly assigned into 2 groups: (i) laser treatment (n = 20), and (ii) control (n = 20). In group (i), patients were given laser treatment and an exercise protocol for 10 sessions during a period of 2 weeks. In group (ii), placebo laser and the same exercise protocol was given for the same period. Patients were evaluated according to the parameters of pain, palpation sensitivity, algometric sensitivity, and shoulder joint range of motion before and after treatment. Analysis of measurement results within each group showed a significant post-treatment improvement for some active and passive movements in both groups, and also for algometric sensitivity in group (i) (p < 0.05 to 0.01). Post-treatment palpation sensitivity values showed improvement in 17 patients (85 %) for group (i) and 6 patients (30 %) for group (ii). Comparison between 2 groups showed superior results (p < 0.01 and p < 0.001) in group (i) for the parameters of passive extension and palpation sensitivity but no significant difference for other parameters. These researchers concluded that this study has shown better results in palpation sensitivity and passive extension, but no significant improvement in pain, active range of motion, and algometric sensitivity in laser treatment group compared to the control group in the patients with shoulder pain.

Markovic and Todorovic (2007) compared the effectiveness of dexamethasone and low-power laser (LPL) after surgical removal of impacted lower third molars under local anesthesia (2 % lidocaine / epinephrine). A total of 120 healthy patients were divided into 4 groups of 30 each: (i) group 1 received LPL irradiation immediately after operation (energy output 4 J/cm² with constant power density of 50 mW, wavelength 637 nm); (ii) group 2 also received intra-muscular (i.m.) injection of 4 mg dexamethasone (Dexason) into the internal pterygoid muscle; (iii) group 3 received LPL irradiation supplemented by systemic dexamethasone, 4 mg i.m. in the deltoid region, followed by 4 mg of dexamethasone intra-orally 6 hours post-operatively; and (iv) control group received only the usual post-operative recommendations (i.e., cold packs, soft diet, etc.). Low-power laser irradiation with local use of dexamethasone (group 2) resulted in a statistically significant reduction of post-operative edema in comparison to the other groups. No adverse effects of the procedure or medication
were observed. The authors concluded that LPL irradiation after lower third molar surgery can be recommended to minimize swelling. The effect is enhanced by simultaneous local intra-muscular use of dexamethasone. The drawbacks of this study were 2-fold: (i) the effects of LPL, if any, was confounded by the simultaneous use of dexamethasone, and (ii) while the combination of LPL and dexamethasone achieved a statistical significant reduction in edema, its clinical benefit is unclear.

Stergioulas (2007) compared the effectiveness of a protocol of combination of laser with plyometric exercises and a protocol of placebo laser with the same program, in the treatment of tennis elbow. A total of 50 patients were randomized into 2 groups: (i) group A (n = 25) was treated with a 904 nm Ga-As laser, frequency 50 Hz, intensity 40 mW and energy density 2.4 J/cm(2), plus plyometric exercises, and (ii) group B (n = 25) that received placebo laser plus the same plyometric exercises. During 8 weeks of therapy, patients of the 2 groups received 12 sessions of laser or placebo, 2 sessions per week (weeks 1 to 4) and 1 session per week (weeks 5 to 8). Pain at rest, at palpation on the lateral epicondyle, during resisted wrist extension, middle finger test, and strength testing was evaluated using visual analog scale (VAS). Also, the grip strength, the range of motion (ROM) and weight test were evaluated. Parameters were determined before treatment, at the end of the 8th week course of treatment (week 8), and 8th (week 8) after the end of treatment. Relative to group B, group A had (i) a significant decrease of pain at rest at the end of 8 weeks of the treatment (p < 0.005) and at the end of following up period (p < 0.05), (ii) a significant decrease in pain at palpation and pain on isometric testing at 8 weeks of treatment (p < 0.05), and at 8 weeks follow-up (p < 0.001), (iii) a significant decrease in pain during middle finger test at the end of 8 weeks of treatment (p < 0.01), and at the end of the follow-up period (p < 0.05), (iv) a significant decrease of pain during grip strength testing at 8 weeks of treatment (p < 0.05), and at 8 weeks follow-up (p < 0.001), (v) a significant increase in the wrist ROM at 8 weeks follow-up (p < 0.01), (vi) an increase in grip strength at 8 weeks of treatment (p < 0.05) and at 8 weeks follow-up (p < 0.01), and (vii) a significant increase in weight-test at 8 weeks of treatment (p < 0.05) and at 8 weeks follow-up (p < 0.005). The authors concluded that these findings suggested that the combination of laser with plyometric exercises was more effective treatment than placebo laser with the same plyometric exercises at the end of the treatment as well as at the follow-up. Moreover, they stated that future studies are needed to establish the relative and absolute effectiveness of the above protocol.

Kaviani and colleagues (2006) examined the effects of low-level laser therapy (LLLT) in the treatment of post-mastectomy lymphedema. A total of 11 women with unilateral post-mastectomy lymphedema were enrolled in a double-blind controlled trial. Patients were randomly assigned to laser and sham groups and received laser or placebo irradiation (Ga-As laser device with a wavelength of 890 nm and fluence of 1.5 J/cm2) over the arm and axillary areas. Changes in patients' limb circumference, pain score, ROM, heaviness of the affected limb, and desire to continue the treatment were measured before the treatment and at follow-up sessions (weeks 3, 9, 12, 18, and 22) and were compared to pre-treatment values. Results showed that of the 11 enrolled patients, 8 completed the treatment sessions. Reduction in limb circumference was detected in both groups, although it was more pronounced in the laser group up to the end of 22nd week. Desire to continue treatment at each session and baseline score in the laser group was greater than in the sham group in all sessions. Pain reduction in the laser group was more than in the sham group except for the weeks 3 and 9. No substantial
differences were seen in other 2 parameters between the 2 treatment groups. The authors concluded that despite the encouraging results, further studies of the effects of LLLT in management of post-mastectomy lymphedema should be undertaken to determine the optimal physiological and physical parameters to obtain the most effective clinical response.

In a systematic review of common conservative therapies for arm lymphoedema secondary to breast cancer treatment, Moseley et al (2007) stated that secondary arm lymphoedema is a chronic and distressing condition which affects a significant number of women who undergo breast cancer treatment. A number of health professional and patient instigated conservative therapies have been developed to help with this condition, but their comparative benefits are not clearly known. This systematic review undertook a broad investigation of commonly instigated conservative therapies for secondary arm lymphoedema including; complex physical therapy, manual lymphatic drainage, pneumatic pumps, oral pharmaceuticals, LLLT, compression bandaging and garments, limb exercises and limb elevation. It was found that the more intensive and health professional based therapies, such as complex physical therapy, manual lymphatic drainage, pneumatic pump and laser therapy generally yielded the greater volume reductions, whilst self-instigated therapies such as compression garment wear, exercises and limb elevation yielded smaller reductions. All conservative therapies produced improvements in subjective arm symptoms and quality of life issues, where these were measured. Despite the identified benefits, there is still the need for large scale, high level clinical trials in this area.

Information on lymphedema from the BC Cancer Agency (2007) notes that laser therapy "may or may not work but need[s] further study."

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 cm² instead of 0.5 to 2.0 cm² for class III lasers) and a larger surface treatment area (cover up to 77 cm² instead of 0.3 to 5.0 cm² for class III lasers). Despite little scientific support, high-power lasers have been employed for various indications including musculoskeletal disorders (e.g., carpal tunnel syndrome and lateral epicondylitis), pain relief, and wound healing. Plaghki and Mouraux (2005) noted that laser heat stimulators selectively activate Adelta and C-nociceptors in the superficial layers of the skin. Their high-power output produces steep heating ramps, which improve synchronization of afferent volleys and thus allow the recording of time-locked events (e.g., laser-evoked brain potentials). Study of the electrical brain activity evoked by Adelta- and C-nociceptor afferent volleys revealed the existence of an extensive, sequentially activated, cortical network. These electro-physiological responses are modulated by stimulus-driven and, even more extensively, top-down processes. The specificity and validity of these components for pain research are currently under intense scrutiny.

In a systematic review on treatment of pressure ulcers, Reddy and colleagues (2008) concluded that there is little evidence to support routine nutritional supplementation or adjunctive therapies including laser therapy compared with standard care.

Carrasco et al (2009) noted that limited studies have demonstrated that LLLT may have a therapeutic effect on the treatment of myofascial pain syndrome (MPS). In this study, 60 patients with MPS and having 1 active trigger point in the anterior
masseter and anterior temporal muscles were selected and assigned randomly to 6 groups (n = 10 in each group): Groups I to III were treated with GaAlAs (780 nm) laser, applied in continuous mode and in a meticulous way, twice-weekly, for 4 weeks. Energy was set to 25 J/cm², 60 J/cm² and 105 J/cm², respectively. Groups IV to VI were treated with placebo applications, simulating the same parameters as the treated groups. Pain scores were assessed just before, then immediately after the 4th application, immediately after the 8th application, at 15 days and 1 month following treatment. A significant pain reduction was observed over time (p < 0.001). The analgesic effect of the LLLT was similar to the placebo groups. The authors stated that using the parameters described in this experiment, LLLT was effective in reducing pain experienced by patients with MPS. Thus, it was not possible to establish a treatment protocol.

Yelden and colleagues (2009) examined the effectiveness LLLT in addition to exercise program on shoulder function in subacromial impingement syndrome (SAIS). A total of 67 patients with SAIS were randomly assigned to either a group that received laser (n = 34) or a group that received placebo laser (n = 26). Pain, functional assessment, disability and muscle strength of shoulder were assessed before and after a 3-week rehabilitation program. Besides laser or placebo laser, superficial cold and progressive exercise program were administered to both groups, 5 days a week, for 3 weeks. A progressive exercise program that was done twice-daily under supervision in clinic and at home was given to the patients. After the treatment, all outcome measurements had shown significant improvement except muscle strength in both the groups. When the parameters of the improvement were compared, there were no significant differences between the 2 groups after treatment. The authors concluded that there is no fundamental difference between LLLT and placebo LLLT when they are supplementing an exercise program for rehabilitation of patients with shoulder impingement syndrome.

In a prospective, randomized double-blind study, Teggi et al (2009) examined the effectiveness of LLLT for tinnitus. A total of 60 outpatients with tinnitus presenting sensorineural hearing loss in the affected ear were included in the study. They were randomly divided into 2 groups: (i) active laser therapy 20 mins a day for 3 months with a 650-nm, 5-mW soft laser (group L), and (ii) control group with dummy device, which duplicated all aspects of active laser therapy except for the activation of the laser beam. One subject in both groups dropped out due to an increase in tinnitus loudness. Two more patients in each group ceased to comply with the protocol due to familiar problems. Main outcome measure was the Tinnitus Handicap Inventory (THI); no statistical difference was detected between the 2 groups in the THI total score (p = 0.97), and its functional (p = 0.89), emotional (p = 0.89) and catastrophic (p = 0.89) subscales. Moreover, a VAS for self-perceived loudness of the tinnitus showed no difference between the groups (p = 0.69). Regarding psychoacoustic parameters, the minimum masking level showed no difference (p = 0.42), while loudness expressed in sensation level exhibited lower values in the treatment group (p = 0.0127). Subjects in the treatment group also reported a decreased rate of hyper-acusis (p = 0.02). No changes were detected in the audiometric threshold in both groups. The authors concluded that soft laser therapy demonstrated no efficacy as a therapeutic measure for tinnitus.

A systematic evidence review by Chow et al (2009) concluded that low-LLLT reduced pain immediately after treatment in acute neck pain, and up to 22 weeks after completion of treatment, in patients with chronic neck pain. The authors included
randomized controlled trials (RCTs) or quasi-RCTs of LLLT, for participants aged 16 or over with acute or chronic neck pain, were eligible for inclusion. Sixteen RCTs (n = 820 participants) met inclusion criteria, with sample sizes ranging from 20 to 90 participants. The authors reported significant effects of LLLT on acute and chronic neck pain. An evaluation of the systematic evidence review by Chow et al by the Centre for Reviews and Dissemination (2009) found that, although suitable methods were employed to reduce the risks of reviewer error and bias for the processes of study selection and data extraction, the authors did not report on whether such methods were used to assess study quality, which was assessed using the Jadad scale. The CRD also found that this did not assess methods of allocation concealment, so the risk on investigator bias affecting trial results could not be ruled out. Furthermore, no information was provided on the actual levels of withdrawals and drop-outs. The CRD also found that all trials included in this systematic review had relatively small sample sizes and information was not provided on whether treatment groups (in individual trials) were comparable at baseline for likely confounders. The CRD noted that the authors of the systematic review acknowledged the considerable clinical heterogeneity in laser treatment parameters, but this also seemed apparent with regard to the sites treated, diagnoses, frequencies of treatment, and uses of cointerventions; it is therefore questionable whether meta-analysis was the most appropriate method of synthesis. The CRD concluded: "Although many aspects of this review were well-conducted, the considerable clinical heterogeneity seen, coupled with uncertainty regarding possible bias in the small trials included, mean the authors' conclusions should be interpreted with a degree of caution."

In a randomized, double-blind, placebo-controlled study, Ay and colleagues (2010) compared the effectiveness of LLLT on pain and functional capacity in patients with acute and chronic low back pain caused by lumbar disk herniation (LDH). A total of 40 patients with acute (26 females/14 males) and 40 patients with chronic (20 females/20 males) low back pain caused by LDH were included in the study. Patients were randomly allocated into 4 groups: (i) group 1 (acute LDH, n = 20) received hot-pack + laser therapy; (ii) group 2 (chronic LDH, n = 20) received hot-pack + laser therapy; (iii) group 3 (acute LDH, n = 20) received hot-pack + placebo laser therapy, and (iv) group 4 (chronic LDH, n = 20) received hot-pack + placebo laser therapy, for 15 sessions during 3 weeks. Assessment parameters included pain, patients' global assessment, physician's global assessment, and functional capacity. Pain was evaluated by VAS. Patients' and physician's global assessment were also measured with VAS. Modified Schober test and flexion and lateral flexion measures were used in the evaluation of ROM of lumbar spine. Roland Disability Questionnaire (RDQ) and Modified Oswestry Disability Questionnaire (MODQ) were used in the functional evaluation. Measurements were done before and after 3 weeks of treatment. After the treatment, there were statistically significant improvements in pain severity, patients' and physician's global assessment, ROM, RDQ scores, and MODQ scores in all groups (p < 0.05). However, no significant differences were detected between 4 treatment groups with respect to all outcome parameters (p > 0.05). There were no differences between laser and placebo laser treatments on pain severity and functional capacity in patients with acute and chronic low back pain caused by LDH.

In a randomized double-blind controlled trial, Meireles and associates (2010) assessed the effectiveness of LLLT on pain reduction and improvement in function in the hands of patients with rheumatoid arthritis. A total of 82 patients with rheumatoid
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arthritis were included in this study. The experimental group was submitted to the application of laser therapy, whereas the control group received a placebo laser. Aluminum gallium arsenide laser was used, at a wavelength of 785 nm, dose of 3 J/cm² and mean power of 70 mW. The groups were homogenous at the beginning of the study with regard to the main variables (p > 0.05). There were no statistically significant differences between groups in most of the measurements taken at the end of the intervention including the primary variables; the following variables were the exceptions: favoring the experimental group -- inflammation of the inter-phalangeal joint of the right thumb (p = 0.012) and perimetry of the inter-phalangeal joint of the left thumb (p = 0.013); and favoring the control group -- flexion of the proximal inter-phalangeal joint of the right fifth finger (p = 0.021), perimetry of the third proximal inter-phalangeal joint of the right hand (p = 0.044), grip strength in the left hand (p = 0.010), and the work domain of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (p = 0.010). The authors concluded that low-level aluminum gallium arsenide laser therapy is not effective at the wavelength, dosage, and power studied for the treatment of hands among patients with rheumatoid arthritis.

The Blue Cross and Blue Shield Association Technology Evaluation Center (2010) concluded that LLLT for either carpal tunnel syndrome or for chronic neck pain does not meet the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria. Furthermore, the Work Loss Data Institute's clinical practice guideline on "Carpal tunnel syndrome" (2011) does not recommend LLLT as a therapeutic option.

Kadhim-Saleh et al (2013) examined the effectiveness of LLLT in reducing acute and chronic neck pain as measured by the VAS. A systematic search of 9 electronic databases was conducted to identify original articles. For study selection, 2 reviewers independently assessed titles, abstracts, and full text for eligibility. Methodological quality was assessed using the Detsky scale. Data were analyzed using random-effects model in the presence of heterogeneity and fixed-effect model in its absence. Heterogeneity was assessed using Cochran's Q statistic and quantifying I². Risk ratios (RR) with 95% confidence intervals (CI) were reported. Eight RCTs involving 443 patients met the strict inclusion criteria. Inter-rater reliability for study selection was 92.8% (95% CI: 80.9 to 100%) and for methodological quality assessment was 83.9% (95% CI: 19.4 to 96.8%). Five trials included patients with cervical myofascial pain syndrome (CMPS), and 3 trials included different patient populations. A meta-analysis of 5 CMPS trials revealed a mean improvement of VAS score of 10.54 with LLLT (95% CI: 0.37 to 20.71; heterogeneity I² = 65%, p = 0.02). The authors concluded that this systematic review provided inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. They stated that the benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference.

van Middelkoop et al (2011) determined the effectiveness of physical and rehabilitation interventions (i.e. exercise therapy, back school, transcutaneous electrical nerve stimulation (TENS), LLLT, education, massage, behavioral treatment, traction, multi-disciplinary treatment, lumbar supports, and heat/cold therapy) for chronic low back pain (LBP). The primary search was conducted in MEDLINE, EMBASE, CINAHL, CENTRAL, and PEDro up to 22 December 2008. Existing Cochrane reviews for the individual interventions were screened for studies fulfilling the inclusion criteria. The search strategy outlined by the Cochrane Back
Review Groups (CBRG) was followed. The following were included for selection criteria: (i) RCTs, (ii) adult (greater than or equal to 18 years) population with chronic (greater than or equal to 12 weeks) non-specific LBP, and (iii) evaluation of at least one of the main clinically relevant outcome measures (pain, functional status, perceived recovery, or return to work). Two reviewers independently selected studies and extracted data on study characteristics, risk of bias, and outcomes at short, intermediate, and long-term follow-up. The GRADE approach was used to determine the quality of evidence. In total, 83 RCTs met the inclusion criteria: exercise therapy (n = 37), back school (n = 5), TENS (n = 6), LLLT (n = 3), behavioral treatment (n = 21), patient education (n = 1), traction (n = 1), and multi-disciplinary treatment (n = 6). Compared to usual care, exercise therapy improved post-treatment pain intensity and disability, and long-term function. Behavioral treatment was found to be effective in reducing pain intensity at short-term follow-up compared to no treatment/waiting list controls. Finally, multi-disciplinary treatment was found to reduce pain intensity and disability at short-term follow-up compared to no treatment/waiting list controls. Overall, the level of evidence was low. Evidence from RCTs demonstrated that there is low quality evidence for the effectiveness of exercise therapy compared to usual care, there is low evidence for the effectiveness of behavioral therapy compared to no treatment and there is moderate evidence for the effectiveness of a multi-disciplinary treatment compared to no treatment and other active treatments at reducing pain at short-term in the treatment of chronic LBP. Based on the heterogeneity of the populations, interventions, and comparison groups, the authors concluded that there are insufficient data to draw firm conclusion on the clinical effect of back schools, LLLT, patient education, massage, traction, superficial heat/cold, and lumbar supports for chronic LBP.

Lake and Wofford (2011) examined the effectiveness of therapeutic modalities for the treatment of patients with patella-femoral pain syndrome (PFPS). Medline was searched using the following databases: PubMed, CINAHL, Web of Science Citation Index, Science Direct, ProQuest Nursing & Allied Health, and Your Journals@OVID. Selected studies were RCTs that used a therapeutic modality to treat patients with PFPS. The review included articles with all outcome measures relevant for the PFPS patient: knee extension and flexion strength (isokinetic and isometric), patella-femoral pain assessment during activities of daily life, functional tests (e.g., squats), Kujala patella-femoral score, and electromyographic recording from knee flexors and extensors and quadriceps femoris cross-sectional areas. Authors conducted independent quality appraisals of studies using the PEDro Scale and a system designed for analysis of studies on interventions for patella-femoral pain. A total of 12 studies met criteria: 1 on the effects of cold and ultrasound together, ice alone, iontophoresis, and phonophoresis; 3, neuromuscular electrical stimulation; 4, electromyographic biofeedback; 3, electrical stimulation for control of pain; and 1, laser. Most studies were of low to moderate quality. Some reported that therapeutic modalities, when combined with other treatments, may be of some benefit for pain management or other symptoms. There was no consistent evidence of any beneficial effect when a therapeutic modality was used alone. Studies did not consistently provide added benefit to conventional physical therapy in the treatment of PFPS. The authors concluded that none of the therapeutic modalities reviewed has sound scientific justification for the treatment of PFPS when used alone.

The American College of Occupational and Environmental Medicine’s clinical guideline on “Elbow disorders” (ACOEM, 2012) listed low-level laser therapy as one
of the interventions/procedures that were considered, but are not currently recommended.

de Carvalho Pde et al (2012) noted that LLLT has been widely used as adjuvant strategy for treatment of musculo-skeletal disorders. The light-tissue interaction (photo-biostimulation) promotes analgesic and anti-inflammatory effects and improves tissue healing, which could justify the recommendation of this therapy for patients with fibromyalgia, leading to an improvement in pain and possibly minimizing social impact related to this disease. These researchers proposed to evaluate the effect of LLLT on tender points in patients with fibromyalgia, correlating this outcome with quality of life and sleep. A total of 120 patients with fibromyalgia will be treated at the Integrated Health Center and the Sleep Laboratory of the Post Graduate Program in Rehabilitation Sciences of the Nove de Julho University located in the city of Sao Paulo, Brazil. After fulfilling the eligibility criteria, a clinical evaluation and assessments of pain and sleep quality will be carried out and self-administered quality of life questionnaires will be applied. The 120 volunteers will be randomly allocated to an intervention group (LLLT, n = 60) or control group (CLLLT, n = 60). Patients from both groups will be treated 3 times per week for 4 weeks, totaling 12 sessions. However, only the LLLT group will receive an energy dose of 6 J per tender point. A standardized 50-min exercise program will be performed after the laser application. The patients will be evaluated regarding the primary outcome (pain) using the following instruments: VAS, McGill Pain Questionnaire and pressure algometry. The secondary outcome (quality of life and sleep) will be assessed with the following instruments: Medical Outcomes Study 36-item Short-Form Health Survey, Fibromyalgia Impact Questionnaire, Berlin Questionnaire, Epworth Sleepiness Scale and polysomnography. ANOVA test with repeated measurements for the time factor will be performed to test between-groups differences (followed by the Tukey-Kramer post hoc test), and a paired t-test will be performed to test within-group differences. The level of significance for the statistical analysis will be set at 5 % (p ≤ 0.05).

Winkelmann et al (2012) stated that the scheduled update to the German S3 guidelines on fibromyalgia syndrome by the Association of the Scientific Medical Societies was planned starting in March 2011. The development of the guidelines was coordinated by the German Interdisciplinary Association for Pain Therapy, 9 scientific medical societies, as well as 2 patient self-help organizations. Eight working groups with a total of 50 members were evenly balanced in terms of gender, medical field, potential conflicts of interest and hierarchical position in the medical and scientific fields. Literature searches were performed using the Medline, PsycInfo, Scopus and Cochrane Library databases (until December 2010). The grading of the strength of the evidence followed the scheme of the Oxford Center for Evidence-Based Medicine. The formulation and grading of recommendations was accomplished using a multi-step, formal consensus process. The guidelines were reviewed by the boards of the participating scientific medical societies. The authors concluded that low-to-moderate intensity aerobic exercise and strength training are strongly recommended; chiropractic, laser therapy, magnetic field therapy, massage, and transcranial current stimulation are not recommended.

In a meta-analysis, Sgolastra et al (2013) evaluated the effectiveness of lasers in reducing dentin hypersensitivity (DH) as compared with placebo or no treatment. Seven electronic databases and a manual search resulted in 2,538 unique publications. After selection, 13 studies were included in the meta-analysis. A
CONSORT-based quality assessment revealed that 3 and 10 studies were at low- and high-risk of bias, respectively. A random-effects model with the generic inverse variance standardized mean difference (SMD) was used because of expected heterogeneity. Meta-analyses of the baseline-end of follow-up changes in pain revealed no differences for Er,Cr:YSSG versus placebo (SMD = 2.49; 95 % CI: -0.25 to 5.22; p = 0.07) but did reveal differences in favor of lasers for Er:YAG versus placebo (SMD, 2.65; 95 % CI: 1.25 to 4.05; p = 0.0002), Nd:YAG versus placebo (SMD, 3.59; 95 % CI: 0.49 to 6.69; p = 0.02), and GaAlAs versus placebo (SMD, 3.40; 95 % CI: 1.93 to 4.87; p < 0.00001). High and significant heterogeneity was found for all comparisons. The authors concluded that Er:YAG, Nd:YAG, and GaAlAs lasers appear to be effective in reducing DH. However, given the high heterogeneity of the included studies, future RCTs are needed to confirm these results.

In a Cochrane review, Peters et al (2013) reviewed the effectiveness of rehabilitation following carpal tunnel syndrome (CTS) surgery compared with no treatment, placebo, or another intervention. On April 3, 2012, these investigators searched the Cochrane Neuromuscular Disease Group Specialized Register (April 3, 2012), CENTRAL (2012, Issue 3), MEDLINE (January 1966 to March 2012), EMBASE (January 1980 to March 2012), CINAHL Plus (January 1987 to March 2012), AMED (January 1985 to April 2012), LILACS (January 1982 to March 2012), PsycINFO (January 1806 to March 2012), PEDRO (January 29, 2013) and clinical trials registers (January 29, 2013). Randomized or quasi-randomized clinical trials that compared any post-operative rehabilitation intervention with no intervention, placebo or another post-operative rehabilitation intervention in individuals who had undergone CTS surgery were selected for analysis. Two reviewers independently selected trials for inclusion, extracted data and assessed the risk of bias according to standard Cochrane methodology. These researchers included 20 trials with a total of 1,445 participants. They studied different rehabilitation treatments including immobilization using a wrist orthosis, dressings, exercise, controlled cold therapy, ice therapy, multi-modal hand rehabilitation, laser therapy, electrical modalities, scar desensitization, and arnica. Three trials compared a rehabilitation treatment to a placebo comparison; 3 trials compared rehabilitation to a no treatment control; 3 trials compared rehabilitation to standard care; and 14 trials compared various rehabilitation treatments to one another. Overall, the included studies were very low in quality. Eleven trials explicitly reported random sequence generation and, of these, 3 adequately concealed the allocation sequence. Four trials achieved blinding of both participants and outcome assessors. Five studies were at high-risk of bias from incompleteness of outcome data at one or more time intervals. Eight trials had a high-risk of selective reporting bias. The trials were heterogeneous in terms of the treatments provided, the duration of interventions, the nature and timing of outcomes measured and setting. Therefore, these researchers were not able to pool results across trials. Four trials reported the authors’ primary outcome, change in self-reported functional ability at 3 months or longer. Of these, 3 trials provided sufficient outcome data for inclusion in this review. One small high quality trial studied a desensitization program compared to standard treatment and revealed no statistically significant functional benefit based on the Boston Carpal Tunnel Questionnaire (BCTQ) (MD -0.03; 95 % CI: -0.39 to 0.33). One moderate quality trial assessed participants 6 months post-surgery using the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire and found no significant difference between a no formal therapy group and a 2-week course of multi-modal therapy.
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commenced at 5 to 7 days post-surgery (MD 1.00; 95 % CI: -4.44 to 6.44). One very low quality quasi-randomized trial found no statistically significant difference in function on the BCTQ at 3 months post-surgery with early immobilization (plaster wrist orthosis worn until suture removal) compared with a splint and late mobilization (MD 0.39; 95 % CI: -0.45 to 1.23). The differences between the treatments for the secondary outcome measures (change in self-reported functional ability measured at less than 3 months; change in CTS symptoms; change in CTS-related impairment measures; presence of iatrogenic symptoms from surgery; return to work or occupation; and change in neurophysiological parameters) were generally small and not statistically significant. Few studies reported adverse events. The authors concluded that there is limited and, in general, low-quality evidence for the benefit of the reviewed interventions. People who have had CTS surgery should be informed about the limited evidence of the effectiveness of post-operative rehabilitation interventions. Until the results of more high-quality trials that evaluate the safety and effectiveness of various rehabilitation treatments have been reported, the decision to provide rehabilitation following CTS surgery should be based on the clinician's expertise, the patient's preferences and the context of the rehabilitation environment. It is important for researchers to identify patients who respond to a certain treatment and those who do not, and to undertake high-quality studies that evaluate the severity of iatrogenic symptoms from the surgery, measure function and return-to-work rates, and control for confounding variables.

de Paula Eduardo et al (2014) noted that recurrent herpes labialis is a worldwide lifelong oral health problem that remains unsolved. It affects approximately 1/3 of the world population and causes frequent pain and discomfort episodes, as well as social restriction due to its compromise of esthetic features. In addition, the available anti-viral drugs have not been successful in completely eliminating the virus and its recurrence. Currently, different kinds of laser treatment and different protocols have been proposed for the management of recurrent herpes labialis. These investigators reviewed the literature regarding the effects of laser irradiation on recurrent herpes labialis and identified the indications and most successful clinical protocols. The literature was searched with the aim of identifying the effects on healing time, pain relief, duration of viral shedding, viral inactivation, and interval of recurrence. According to the literature, none of the laser treatment modalities is able to completely eliminate the virus and its recurrence. However, laser phototherapy appears to strongly decrease pain and the interval of recurrences without causing any side effects. Photodynamic therapy can be helpful in reducing viral titer in the vesicle phase, and high-power lasers may be useful to drain vesicles. The main advantages of the laser treatment appear to be the absence of side effects and drug interactions, which are especially helpful for older and immune-compromised patients. The authors concluded that although these results indicated a potential beneficial use for lasers in the management of recurrent herpes labialis, they are based on limited published clinical trials and case reports. They stated that the literature still lacks double-blind, controlled clinical trials verifying these effects and such trials should be the focus of future research.

He and co-workers (2013) examined the effectiveness of LLLT in the management of orthodontic pain. This systematic review and meta-analysis was carried out in accordance with Cochrane Handbook and the PRISMA statement. An extensive literature search for RCTs, quasi-RCTs, and controlled clinical trials (CCTs) was performed through CENTRAL, PubMed, Embase, Medline, CNKI, and CBM up to October 2011. Risk of bias assessment was performed via referring to the Cochrane
tool for risk of bias assessment. Meta-analysis was implemented using Review Manager 5.1. As a result, 4 RCTs, 2 quasi-RCTs, and 2 CCTs were selected from 152 relevant studies, including 641 patients from 6 countries. The meta-analysis demonstrated that 24% risk of incidence of pain was reduced by LLLT (RR = 0.76, 95% CI: 0.63 to 0.92, p = 0.006). In addition, compared to the control group, LLLT brought forward "the most painful day" (MD = -0.42, 95% CI: -0.74 to -0.10, p = 0.009). Furthermore, the LLLT group also implied a trend of earlier end of pain compared with the control group (MD = -1.37, 95% CI: -3.37 to 0.64, p = 0.18) and the pseudo-laser group (MD = -1.04, 95% CI: -4.22 to 2.15, p = 0.52). However, the authors concluded that because of the methodological shortcomings and risk of bias of included trials, LLLT was proved with limited evidence in delaying pain onset and reducing pain intensity. Moreover, they stated that in the future, larger and better-designed RCTs are needed to provide clearer recommendations.

Thornton et al (2013) stated that shoulder pain is a common musculo-skeletal condition that affects up to 25% of the general population. Shoulder pain can be caused by any number of underlying conditions including subacromial impingement syndrome, rotator-cuff tendinitis, and biceps tendinitis. Regardless of the specific pathology, pain is generally the number 1 symptom associated with shoulder injuries and can severely affect daily activities and quality of life of patients with these conditions. Two of the primary goals in the treatment of these conditions are reducing pain and increasing shoulder ROM. Conservative treatment has traditionally included a therapeutic exercise program targeted at increasing ROM, strengthening the muscles around the joint, proprioceptive training, or some combination of those activities. In addition, these exercise programs have been supplemented with other interventions including non-steroidal anti-inflammatory drugs, corticosteroid injections, manual therapy, activity modification, and a wide array of therapeutic modalities (e.g., cryotherapy, EMS, ultrasound). Recently, LLLT has been used as an additional modality in the conservative management of patients with shoulder pain. However, the authors noted that true effectiveness of LLLT in decreasing pain and increasing function in patients with shoulder pain is unclear.

Amid et al (2014) reviewed the data published in the field of the effects of LLLT on proliferation and differentiation of the cells contributing in bone regeneration. These researchers performed an electronic search in PubMed from 2001 to April 2014. English language published papers on LLLT were found using the selected keyword. The full texts of potentially suitable articles were obtained for final assessment according to the exclusion and inclusion criteria. A total of 240 articles were found from 2001 to April 2014. Following the initial screening of titles and abstracts as well as the final screening of full texts, 22 articles completely fulfilled the inclusion criteria of this study. Wavelength used in LLLT irradiation varied between 600 to 1,000 nm with an energy density of 0.04 to 60J/cm(2). Although almost all studies agreed on getting positive effects from LLLT, some had opposing results. The authors concluded that low level laser with low-energy density range appears to exert a bio-stimulatory effect on bone tissue, enhance osteoblastic proliferation as well as differentiation on cell lines used in in-vitro studies. They stated that despite the fact that many researches have been recently done on the effects of LLLT on different cell lines, without knowing the precise mechanism and effects, they were not able to offer a clinical treatment protocol.

Beckmann et al (2014) stated that diabetic foot ulcers as one of the most common complications of diabetes mellitus are defined as non-healing or long-lasting chronic
skin ulcers in diabetic patients. Multi-disciplinary care for the diabetic foot is common, but treatment results are often unsatisfactory. 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. A systematic literature review identified 1,764 articles on this topic. These researchers adopted 22 eligible references; 8 of them were cell studies, 6 were animal studies, and 8 were clinical trials. Cell studies and animal studies gave evidence of cellular migration, viability, and proliferation of fibroblast cells, quicker re-epithelization and reformed connective tissue, enhancement of microcirculation, and anti-inflammatory effects by inhibition of prostaglandins, interleukin, and cytokine as well as direct anti-bacterial effects by induction of reactive oxygen species (ROS). The transferal of these data into clinical medicine is under debate. The majority of clinical studies showed a potential benefit of LLLT in wound healing of diabetic ulcers. But there are a lot of aspects in these studies limiting final evidence about the actual output of this kind of treatment method. 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.

Doeuk et al (2015) noted that LLLT is currently being used for various disorders, but with no convincing scientific evidence. Most recently these investigators have noticed an increase in published RCTs that have focused on its applications in wound healing, scarring, disorders of the temporomandibular joint (TMJ), oral mucositis, and dental pain. These researchers evaluated the scientific evidence about its effectiveness in maxillofacial surgery. They reviewed PubMed from January 2003 to January 2013 using the key phrase "low level laser treatment". The inclusion criterion was intervention studies in humans of more than 10 patients. The authors excluded animal studies and papers in languages other than English, French, and German. These researchers found 45 papers that they screened independently. The resulting full texts were scrutinized by 2 authors who awarded a maximum of 5 points using the Jadad scale for assessing the quality of RCT, and extracted the data according to sample size, variables of LLLT, the authors' conclusions, and the significance of the result. The authors concluded that LLLT seems to be effective for the treatment of oral mucositis after treatment for head and neck cancer. However, it cannot yet be considered a valid treatment for disorders of the TMJ; and it seems to improve gingival healing, and myofascial and dental pain.
S8948 Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

054.9 Herpes simplex without mention of complication [herpes labialis]
153.0 - 154.9 Malignant neoplasm of colon, rectum, rectosigmoid junction and anus
330.0 - 337.9 Hereditary and degenerative diseases of the central nervous system
354.0 Carpal tunnel syndrome [rehabilitation following carpel tunnel release]
388.30 - 388.32 Tinnitus
457.0 Postmastectomy lymphedema syndrome
457.1 Other lymphedema
457.2 Lymphangitis
457.8 Other noninfectious disorders of lymphatic channels
457.9 Unspecified noninfectious disorder of lymphatic channels
525.0 - 525.9 Other diseases and conditions of the teeth and supporting structures [orthodontic pain] [dentin hypersensitivity]
611.71 Mastodynia
707.00 - 707.9 Chronic ulcer of skin
710.0 - 739.9 Diseases of musculoskeletal system and connective tissue
870.0 - 897.7 Open wound
998.83 Non-healing surgical wound

The above policy is based on the following references:

17. Puett DW, Griffin MR. Published trials of nonmedicinal and noninvasive therapies for hip and knee osteoarthritis. Ann Intern Med. 1994;121(2):133-140.


