

LOW LEVEL LASER THERAPY (LLLT)

Technology Assessment
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INTRODUCTION

Low level laser therapy (LLLT) is a light source treatment that generates light of a single wavelength. LLLT emits no heat, sound, or vibration. Instead of producing a thermal effect, LLLT may act via nonthermal or photochemical reactions in the cells, also referred to as photobiology or biostimulation.

Laser radiation and monochromatic light may alter cell and tissue function. Laboratory studies suggest that irradiation stimulates collagen production, alters DNA synthesis, and improves the function of damaged neurological tissue. Several mechanisms underlying therapeutic effects with LLLT have been suggested. Theories include:

1. Increased ATP production by the mitochondria and increased oxygen consumption on the cellular level, which may result in muscle relaxation
2. Increased serotonin and increased endorphins
3. Increased anti-inflammatory effects through reduced prostaglandin synthesis
4. Improved blood circulation to the skin in cases like neuralgia and diabetes mellitus
5. Decreases permeability of the membrane of the nerve cells for Na/K causing hyperpolarisation
6. Increased lymphatic flow and decreased edema

LLLT devices include the gallium arsenide (GaAs), gallium aluminum arsenide infrared semiconductor (GaAlAs), and helium neon (HeNe) lasers. The 632.8 nm wavelength HeNe laser emits visible red light and may have a shallow penetration into skin. The GaAlAs, infrared laser has a longer wavelength than red beam laser and may have deeper tissue penetration. The 904 nm wavelength GaAs laser is most commonly used for pain and inflammation because it has the deepest tissue penetration. As a result, it may be less suited for wound healing.

Varying treatment parameters may involve altering pulse rate, applicator placement, wavelength, irradiance (power/unit area), beam divergence, spot size, delivery (fiber optic, direct), polarity, pulse duration, and duty cycle.

Athletic trainers, chiropractors, practitioners of alternative medicines, and physical therapists have used LLLT to treat a variety of disorders. Indications include carpal tunnel syndrome, joint disorders and tendinopathies, lateral and medial epicondylitis, osteoarthritis, low back pain, ankle sprains, venous ulcers, and decubitus ulcers. (Gam 1993) (Mulcahy 1995) (Simunovic 1996) (Schneider 1999) (Naerser 2002) (Gur 2003) (Brosseau 2004) (Lindstrom 2004)

Introduction and FDA Status

Food and Drugs Administration Status

Between 2002 and 2004, the Food and Drug Administration (FDA) granted 510(k) approval to several companies to market lasers that provide LLLT. The LLLT lasers are classified under “Lamp, Non-heating, for Adjunctive Use in Pain Therapy”.

MicroLight Corporation of America received approval on February 6, 2002, for the MicroLight 830. This laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome. (FDA 2002)

Acculaser received approval on July 29, 2002, for Acculaser Pro Low Level Laser Therapy. Acculaser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome. (FDA 2002a)

PhotoThera Incorporated received approval on March 19, 2004 for the Acculaser Pro4. It is indicated for adjunctive use in providing temporary relief of pain associated with iliotibial band syndrome. (FDA 2004)

Meditech International, Inc received approval on April 10, 2003 for the BioFlex Professional Therapy System, which was classified under “Infrared Lamp”. The BioFlex is indicated for “use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue.” (FDA 2003)

CARPAL TUNNEL SYNDROME

Carpal tunnel syndrome (CTS) is an entrapment neuropathy of the median nerve at the wrist caused by compression of the median nerve. Signs and symptoms include paresthesias, numbness and tingling, Tinel sign, Phalen sign, hypoesthesia, nocturnal awakening, pain, and hand weakness. CTS affects workers whose tasks involve repetitive hand movements. Systemic medical disorders like diabetes mellitus, thyroid disease, rheumatoid arthritis, gout, or obesity may also contribute to CTS.

Standard treatments for CTS include conservative treatments and surgical release of the transverse carpal tunnel. Surgical release is performed in 40 to 45% of cases with 460,000 procedures performed each year. After surgery, one third of patients continue to experience pain and functional loss while 40% regain normal function and 5% worsen. (Naerser 2002)

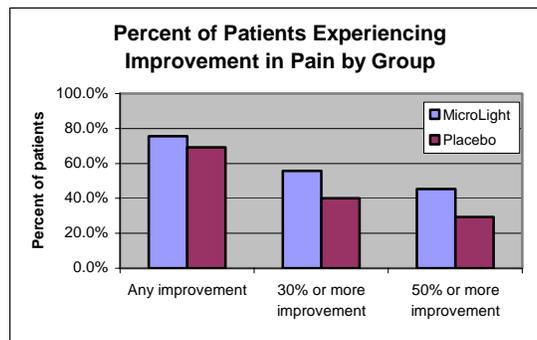
I. Unpublished randomized, placebo-controlled trial

- a. MicroLight conducted a double blind study of LLLT that randomized 135 CTS patients to active LLLT or sham LLLT. Treatment occurred 3 times per week for 5 weeks with follow-up at 1, 6, and 12 weeks. (MicroLight Undated)

Success was defined as a 30% reduction on the pain VAS at 12 weeks.

Study Population: Patients were included in the study if they were diagnosed with moderate to severe CTS with a mean Symptom Severity scale score of at least 2. Patients rated their pain at 30 or more on a 100-point pain VAS and failed one month of conservative therapy. They had not undergone surgery.

Results:



While the percent of successful active laser patients is 15% greater than the percent of successful placebo patients, the report does not indicate whether findings reach statistical significance. In addition, the report does not indicate the number of patients who withdrew or were lost-to-follow-up.

Carpal Tunnel Syndrome

- b. MicroLight provided information regarding a prospective, double blind study conducted at General Motors that determined the efficacy of physical therapy (PT) and active laser compared to PT and sham laser. A 930 nm wavelength laser with mean power output of 90 mW provided LLLT. Subjects continued their current medication regimens. (Anderson Undated)

The study assigned half of the 119 subjects who entered the study to PT and active laser. Patients were evaluated on conduction latencies, grip strength, tactile sensation, carpal tunnel anatomy, and return to work at 5 weeks.

Study Population: The study included patients with CTS based on pain and burning or tingling paresthesias, positive Tinel sign and Phalen test, and abnormal electromyogram (EMG).

	Active treatment	Sham treatment
Number of patients	41	48
Mean age	43.4 years	43.7 years
Previous Hand Surgery	50%	63%

Results: The table shows the percent of patients in each study group that improved in grip strength and range of motion.

	PT and Active Laser	PT and Sham Laser
Grip Strength		
*Flexion	48%	14%
*Extension	41%	11%
*Pinch	28%	15%
Peak Torque	17%	8%
Range of motion		
Flexion	14.1%	1.3%
Extension	11.7%	5%
*Radial Dev	31.2%	-2.9%

* differences between groups were statistically significant

While aspects of grip strength and range of motion reached significance, the study did not detect significant differences between groups on sensory threshold, wrist torque, wrist work velocity, wrist blood flow, or nerve conduction velocities.

72% of the active treatment group returned to work compared to 41% of the sham group. This 31% difference between the groups was significant.

While the study's findings showed better results on some outcomes following active treatment, the report does not indicate the number of patients available at follow-up. In addition, the study reports only the percentage of patients who improved without clearly reporting the extent of improvement.

II. Randomized, placebo-controlled, cross-over trial

- a. Naerser conducted a small, cross-over trial with 11 CTS cases. Seven patients received the sham series first, and 4 patients received the real treatments first. Each patient received 9 to 12 treatments during each 3 to 4 week treatment series. Patients' first posttest score acted as a pretreatment score for the second treatment series. (Naerser 2002)

A licensed acupuncturist administered treatment:

1. TENS was administered at acupuncture point PC 7, the point closest to the median nerve of the wrist crease, and TW4 on the dorsum of the wrist.
2. During TENS treatment, the red beam laser was applied to 6 points on the fingers and 5 to 8 points on the wrist and hand. Points included the center of the distal wrist crease, acupuncture point PC 7, and the point closest to the median nerve of the wrist crease.
3. The infrared laser was applied for one minute at 3 pulse settings to 5 deeper acupuncture points on the upper extremity, including the elbow, shoulder, upper back, and cervical paraspinal areas.

Active treatment involved providing laser treatment at the following parameters.

	Red beam laser	Infrared laser
Laser type	HeNe laser Continuous	Gallium arsenide diode 180-ns pulsed
Wavelength	632.8 nm	904 nm
Power output	15 mW	9.4 W
Diameter	2 mm	5 mm

Microamps TENS at 580 uA to 3.5 mA was applied to the affected wrist. TENS was administered for 2 minutes at a pulsed frequency of 292 Hz followed by 18 minutes at a pulsed frequency of 0.3 Hz.

Sham treatment consisted of blocked laser beams that made a sound every 60 seconds and a TENS device that had been turned off.

The study measured pain with the 78-point MPQ. Follow-up occurred at one week.

Study Population: The study included patients with at least 2 signs: paresthesia, positive Phalen, positive Tinel, nocturnal awakening, hypoesthesia, or wrist and hand pain. Patients were excluded due to cervical radiculopathy, double crush syndrome, or thoracic outlet syndrome.

The 11 patients were also stratified into borderline/mild or moderate CTS based on electrodiagnostic or clinical findings.

	Borderline/mild CTS	Moderate CTS
Median nerve sensory latency	< 3.6 ms	≥ 3.6 ms
Median nerve motor latency	> 4.3 ms	≤ 4.3 ms

Carpal Tunnel Syndrome

Patients had a mean age of 53.5 years and had failed conservative therapy for a mean of 16 months.

Result:

	Pooled real treatment	Pooled sham treatment
Mean sensory peak latency (n=8)		
Pretreatment	3.93	4.03
Posttreatment	3.72	4.03
Mean motor latency (n=11)		
Pretreatment	4.07	4.20
Posttreatment	4.36	4.15
Positive Phalen sign		
Pretreatment	9/11	6/8
Posttreatment	2/11	5/8
Positive Tinel sign		
Pretreatment	6/11	1/8
Posttreatment	0/11	3/8

A placebo effect was observed in 3 of 11 cases. Seven patients reported pain scores that decreased by more than 50% following real LLLT and TENS. All 11 patients resumed their previous work activities.

Patients did not change their medication regimens throughout the study.

Conclusion: LLLT acts as a substitute for surgery when applied in the earlier stages of CTS and with mild to moderate cases.

III. Case Series

- a. Weintraub conducted a case series study of 30 hands with CTS. Patients underwent 15 treatments with a GaAlAs, continuous laser of 830 nm wavelength and 30 mW output. Percutaneous LLLT delivered 9 J/point at 5 points along the median nerve. (Weintraub 1997)

The primary outcome was disappearance of acroparesthesiae for a minimum of 48 hours. Secondary measures included neurological exam changes and improvement in distal latency.

Study Population: The study included patients with compound muscle action potential distal latency greater than 4.0 ms and sensory nerve action potential greater than 3.7 ms.

The 23 patients had a mean age of 52.4 years and a mean duration of symptoms of 24.4 months.

Results: 77% of cases achieved complete resolution of symptoms and abnormal physical findings. Nocturnal complaints were the earliest symptoms to disappear, followed by tingling, stiffness, and weakness.

Carpal Tunnel Syndrome

The study considered 7 hands as treatment failures due to sensory nerve action potential or distal latency greater than 3.7 ms.

Conclusion: Laser neurolysis is a safe and cost-effective alternative therapy producing a 77% success rate.

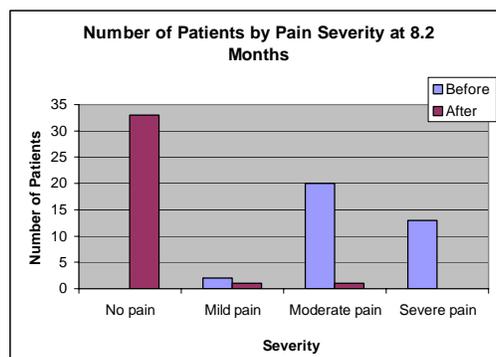
- b. Wong examined the effects of LLLT on CTS or repetitive stress injury with a diode GaAlAs, 830 nm wavelength laser with 100 mW output. The laser probe was directed for 2 to 5 minutes at the spinous processes, especially C5 and T1. The study also worked to correct abnormal posture of the head and neck and work ergonomics. Patients were encouraged to wear a cervical collar and/or a clavicle harness to maintain posture. (Wong 1995)

Pain was graded as mild (unpleasant), moderate (50% incapacitating), or severe (100% incapacitating). Patients underwent an average of 10 treatment sessions with an average follow-up of 8.2 months.

Study Population: The study included 35 female patients diagnosed with CTS or repetitive stress injury. Patients experienced continued pain, numbness, and tingling in one or both hands and fingers. They also had abnormal posture and tenderness of the spinous processes, scapula, and trapezius.

The study subjects' average age was 42.1 years and the average duration of symptoms was 21 months.

Results: The pain, numbness, and tingling in the hands disappeared or subsided following LLLT in all patients. No patients deteriorated in symptoms, and no adverse effects were reported.



Conclusion: LLLT may offer relief of pain for selected patients with CTS and RSI due to soft tissue injuries at the lower cervical and upper thoracic spine.

MUSCULOSKELETAL DISORDERS

Unspecified musculoskeletal disorders

I. Systematic review and meta-analyses

- a. Gam conducted a meta-analysis of the published effect of LLLT on musculoskeletal pain. The analysis included 23 articles published prior to 1991 in English, German, French, Swedish, Norwegian, and Danish. Nine trials were randomized controlled trials in which both evaluator and patient were blinded. (Gam 1993)

The mean difference between treatment and placebo on a pain VAS was 0.3% indicating no effect of LLLT on pain in musculoskeletal syndromes. The differences were not weighted by sample because trials varied in the musculoskeletal diseases treated, LLLT dose, laser type, and wavelength.

II. Randomized double-blind, placebo-controlled trial

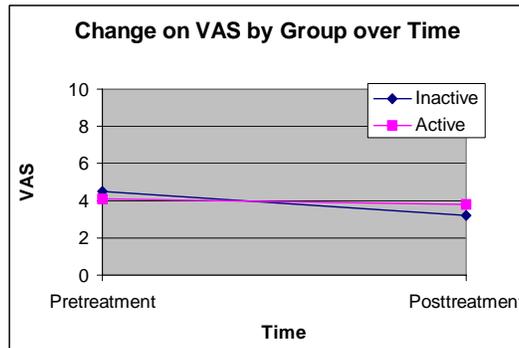
- a. Mulcahy studied the effect of LLLT on localized, painful, soft tissue conditions. LLLT was administered twice weekly for 4 weeks with an energy output of 35 mW and dose of 1 J/ cm². (Mulcahy 1995)

The study measured outcomes with a pain VAS, McGill pain questionnaire, and patients' subjective feelings about treatment.

Study Population: While 23 patients were randomized to active or inactive treatment, 20 patients (mean age 43 years) were included in the analysis.

	Inactive treatment	Active treatment
Plantar fasciitis	1	3
Trochanteric bursitis	2	1
Tendonitis	1	3
Lateral epicondylitis	1	2
Knee pain	2	2
Cervical pain	1	0
Lumbar pain	0	1

Results: 87% of the inactive treatment group felt their pain had improved compared to 42% of the active group. Furthermore, the blinded physiotherapists felt they were getting consistently better results from Machine A, the inactive machine.



Conclusion: The study did not demonstrate any therapeutic effect of laser therapy other than as an elaborate placebo.

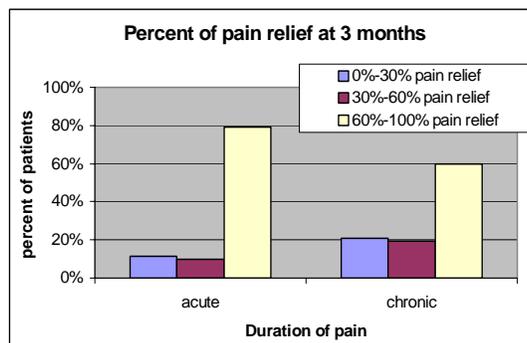
III. Case series

- a. Simunovic's case series evaluated patients following LLLT directed at the target area, painful trigger points, referred areas, and nerve roots. (Simunovic 1996)

The study used an infrared, 830 nm wavelength, continuous wave, diode laser with 120 mW output and spot size of 0.5 cm². Energy doses were increased to a maximum of 60 J depending on patient tolerance. Treatment was administered 5 times per week. If patients' conditions improved, treatment frequency was reduced to 3 times per week.

Study population: The study included 243 patients with bilateral pain. 25.64% of the cases were acute.

Results: At 6 months, 14% of acute cases required new treatment. In chronic cases, 31% required new treatment.



Conclusion: The myofascial pain relief achieved with LLLT corresponded with decreased tension and improvement in functional ability.

- b. McCourt reported the results of 107 subjects with sports and sports-related injuries who underwent a mean of 5.7 LLLT sessions (range 1 to 18 sessions). Treatment began daily and was reduced to every second day or three times per week. The study used the Bioflex Professional Model operating with a 60 diode, multisource treatment array (840 nm, pulsed at 1 kHz, area of 25 cm²) directed at the target tissue. (Mccourt Undated)

Outcomes were measured with a pain VAS at 2 weeks. Failure was defined as less than 10% pain relief.

Study Population: The patients had a mean age of 27.8 years and represented 136 diagnoses under the major categories of:

- muscle injuries - 25%
- low back and neck pain - 15.8%
- ankle sprains - 15.8%

Patients were excluded due to active or suspected neoplasm, hemorrhage, or pregnancy.

Of the 101 subjects with 122 diagnoses who completed the study, 61.5 % were chronic cases.

Results: 83.9% of acute cases and 58.7% of chronic cases achieved over 60% pain relief. 7.8% chronic cases were failures v 3.2% of acute cases.

Of the 101 who finished treatments, 93% returned to full training without relapse at 2 weeks post discharge.

Conclusion: Preliminary findings indicate the potential benefit of the device in both acute and chronic sports-related injuries.

Joint disorders and tendinopathies

Chronic joint disorders all involve pain at the articular structures. Disorders include osteoarthritis, TMJ, patellofemoral pain, and spinal disorders.

Bjordal suggests optimal treatment parameters based on common tendon injuries.

	Infrared, continuous GaAlAs, 820-830 nm		Infrared, pulsed GaAs 904 nm		Red, continuous HeNe 904 nm	
	Power Density (W/cm ²)	Dose (J/ cm ²)	Power Density (W/ cm ²)	Dose (J/ cm ²)	Power Density (W/ cm ²)	Dose (J/ cm ²)
Plantar fasciitis	0.01 - 0.20	1.4 - 14	0.004 - 0.2	0.6 - 6	0.03 - 0.60	4.2 - 42
Achilles	0.05 - 0.10	0.7 - 7	0.002 - 0.1	0.3 - 3	0.01 - 0.20	1.4 - 14
Patellar	0.05 - 0.10	0.7 - 7	0.002 - 0.1	0.3 - 3	0.01 - 0.20	1.4 - 14
Epicondylitis	0.05 - 0.10	0.7 - 7	0.002 - 0.1	0.3 - 3	0.01 - 0.20	1.4 - 14
Rotator cuff	0.03 - 0.6	4.2 - 42	0.012 - 0.6	0.4 - 4	0.12 - 0.6	12.6 - 126

(Bjordal 2003)

I. Systematic review and meta-analyses

- a. Bjordal conducted a meta-analysis of LLLT trials for treatment of common tendon injuries. (Bjordal 2001)

Based on a review of in vitro trials of LLLT, Bjordal derived ranges for optimal dose, power density, and treatment frequency:

- dose from 0.1 to 3 J/ cm²
- power density from 5 to 21 mW/ cm²
- treatment frequency from 3 to 5 times per week.

Inclusion Criteria: The review included controlled trials that met the following 7 criteria.

1. diagnosis of tendinopathy
2. exposure area is skin overlying inflammation site
3. intensity of dose according to identified optimal ranges
4. treatment frequency of at least twice weekly and no less than 6 total
5. control group of at least 10 patients that received placebo therapy
6. double-blinded
7. specific endpoints within 2 to 6 weeks after inclusion

The analysis used pain as the primary outcome measure. The effect size was calculated as the difference (%) in mean change from baseline to end point between the active and placebo groups.

Results: The literature search identified 20 trials, but excluded 7 for not meeting criteria. The included trials treated epicondylitis (n=7), rotator cuff injury (n=5), patellar injury (n=1), achilles injury (n=2), and plantar fasciitis (n=1). Patients mainly consisted of subacute and long-lasting cases with a 3 to 4 month average duration of symptoms.

The 9 trials that used the suggested optimal parameters showed a weighted mean difference of 32% in favor of active LLLT. If the 4 trials without optimal treatment parameters were included in the pooling, the effect size decreased to 22.1% over placebo.

Four of the nine trials were evaluated as being of good or of acceptable methodological quality.

Conclusion: LLLT has a credible biological action on tendon tissue when used with power density and dose within a suggested optimal range. Nine RCT, the majority of acceptable methodological quality, have shown a significant effect of LLLT of about 32%.

- b. Bjordal conducted a meta-analysis testing the hypothesis that LLLT of the joint capsule reduces pain in chronic joint disorders if the dose is adjusted to inhibit inflammatory activity. (Bjordal 2003)

Inclusion criteria: Eligible studies were double-blind, randomized, placebo-controlled trials published between 1980 and November 2001. The study populations in the trials included patients with joint disorders of more than 6 months duration or osteoarthritis verified by x-ray. LLLT was directed at the skin overlying the inflammatory joint capsule.

The main outcome was pain as measured on a VAS and calculated as weighted mean differences. Secondary outcome was change in global health status. Improved and not improved ratings were pooled and expressed as relative risk.

Results: Of the 88 RCT involving LLLT, 20 trials addressed chronic joint disorders. 6 trials were excluded for not irradiating over the joint capsule. The remaining 14 trials included a total of 695 patients.

Seven trials provided LLLT within the suggested treatment parameters. Pooled data indicated a weighted mean difference of 29.8 mm out of 100 mm on the pain VAS. This significantly favored active laser.

Five trials working within the suggested parameters reported health status improvement. Pooled estimates of health status change were significantly in favor of active LLLT with a relative risk of 0.52.

Bjordal comments that the weakest aspect of the review is the heterogeneity in treatment procedures and patient sample. For example, baseline pain for patients ranged from 35 to 82 out of 100.

Conclusion: Although heterogeneity calls for caution in interpretation, LLLT seems effective in reducing pain from chronic joint disorders.

Lateral and Medial Epicondylitis

I. Randomized, double-blind, placebo-controlled trials

- a. Vasseljen conducted a study using a 904 nm wavelength, GaAs laser with 12 diodes covering 20 cm². LLLT was provided at a distance of 8 mm from the skin for 10 minutes for a dose of 3.5 J/cm². After dividing patients into acute and chronic cases, patients were randomized to active laser or placebo laser. Sessions occurred 3 times per week for a total of 8 treatments. (Vasseljen 1992)

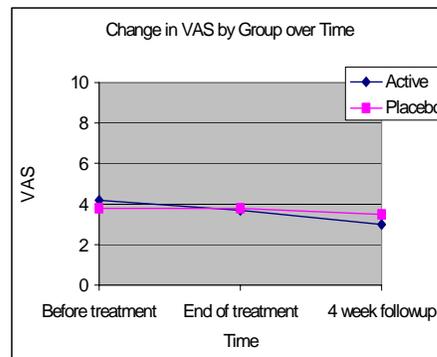
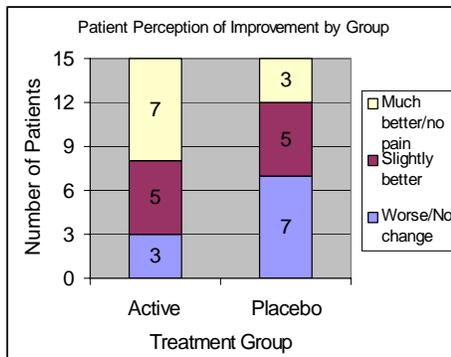
Maximum grip strength, ability to lift 3 kg in wrist extension, wrist flexion to the point of aggravation, and pain with a 10-point VAS measured outcomes.

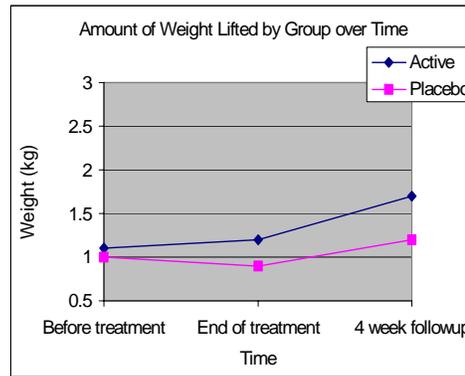
Study Population: The study included 30 patients with lateral epicondylitis confined to the tenoperiosteal junction of the extensor carpi radialis brevis.

Patients were excluded due to arthrogenic, neurogenic, or muscular dysfunction in the cervical area. Patients were also excluded due to rheumatoid arthritis, bilateral epicondylitis, or other treatment in the previous 3 weeks.

	Active (n=15)	Placebo (n=15)
Average age	47.1 years	43.9 years
Average duration of symptoms	4.1 months	2.9 months
Previous treatments	8	9

Results: The active laser group showed a significant decrease on the pain VAS over the placebo group from inclusion to the end of treatment and from inclusion to the 4-week follow-up.





Conclusion: LLLT was shown to have an effect over placebo, however, as a sole treatment for lateral epicondylitis, it is of limited value.

II. Case series with a comparison group

- a. Simunovic conducted a multi-center trial to evaluate the effect of LLLT on epicondylitis. The study compared 2 methods of application. The skin contact technique involves irradiating trigger points or tender points. The non-contact scanning technique involves irradiating an area from a distance of 5 cm at a speed of 0.02 m/s. (Simunovic 1998)

Patients with bilateral symptoms all underwent trigger point technique. Patients with unilateral symptoms were randomly allocated to trigger point technique, scanner treatment, or a combination of techniques.

Patients underwent daily sessions 5 times per week. Frequency reduced to 1 to 2 treatments per week for acute cases and 3 treatments per week for chronic cases.

	Switzerland	Croatia
Number of patients	234	90
Number acute cases (<3 months)	69	36
Number chronic cases (>3 months)	165	54
Number of bilateral cases	25	16
Types of Lasers	<ol style="list-style-type: none"> 1. Infrared diode (830 nm, continuous wave, 120 mW, 5 mm diameter) 2. Infrared diode (904 nm, pulsed wave, 30 mW) combined with HeNe laser (632.8 nm, 10 mW, 2 mm diameter) 	<ol style="list-style-type: none"> 1. Infrared diode (830 nm, continuous wave, 120 mW, 5 mm diameter) 2. Infrared diode (904 nm, pulsed wave, 10 mW) combined with HeNe laser (632.8 nm, 10 mW, 2 mm diameter)

The study employed the following treatment parameters.

Dose (J/TP)	Max Dosage for TP (J/cm ²)	Max Dosage for Scanner (J/cm ²)	Treatments per Week	No of Total Treatments
2.5 to 4	10	12	3 to 5	6 to 24

Study population: The study included patients with medial and lateral epicondylitis. Chronic cases failed previous conservative therapy.

Patients were excluded due to conditions arising from cervical spinal disorder, malignant tumor, or epilepsy.

Results:

		Unilateral (n=44)		Bilateral (n=25)
		Scanner technique (n=22)	Trigger point + Scanner (n=22)	Trigger point
Switzerland	60%-100% pain relief	18	22	25
	0%-60% pain relief	4		
Croatia		Unilateral (n=20)		Bilateral (n=16)
		Scanner technique (n=10)	Trigger point + Scanner (n=10)	Trigger point
	60%-100% pain relief	5	10	16
	0%-60% pain relief	5		

Conclusion: The study suggested that trigger point technique was more effective than scanner method alone. Combining techniques showed the best results, but not on a significant level.

Osteoarthritis

A large number of treatments are available for osteoarthritis, ranging from pharmacological interventions such as analgesics to surgical interventions such as hip replacement. (Brosseau 2004)

I. Systematic review and meta-analysis

- a. Brosseau conducted a meta-analysis to determine the effectiveness of laser therapy for osteoarthritis of the hand, knee, and hip. The study also endeavored to determine the most effective method of administering LLLT for osteoarthritis, including the optimal wavelength, dosage, application technique, and length of treatment. (Brosseau 2004)

Inclusion criteria: Eligible studies included RCT or controlled clinical trials published through December 31, 2002, that treated patients with osteoarthritis. Trials that compared LLLT with one standard treatment were included.

The primary measure of effectiveness was pain relief. Secondary outcomes included physical function, patient global assessment, joint imaging, articular mobility, muscular testing, systemic components, medication usage, and adverse side effects.

The researchers calculated weighted mean differences for continuous data, standardized mean differences when different scales were used, and odds ratio for dichotomous data.

Results: Of the 142 potential articles, 5 trials met inclusion criteria. On a 5-point quality scale, the studies had a median score of 3 with a range from 1 to 4.

Two trials used the He-Ne laser of 632.8 nm wavelength. One trial used a 904 nm wavelength space laser, and two trials used the 830 nm wavelength GaAs laser.

The trials studied osteoarthritis of the thumb (n=1), knee (n=3), and unspecified locations (n=1). Three trials administered 2 to 3 treatment sessions per week for 3 to 4 weeks. One trial treated patients twice per day for 10 days while another trial treated patients 3 times per week for 10 weeks.

Of the three trials that randomized patients, 112 patients were randomized to laser and 85 patients received sham or placebo laser.

The analysis found no difference between laser and placebo on pain with a standardized mean difference of -0.23. One trial reported less pain following active laser compared to placebo. Two trials reported no difference in pain between groups. One trial found that 4 out of 5 laser patients reported pain relief compared to 0 out of 3 placebo patients, with an odds ratio of 0.05.

The analysis did not detect a difference in patient assessed global disease, strength, joint mobility, or joint tenderness.

The authors indicate that a limitation of the findings is the heterogeneity of clinical application. The poor quality of the included studies also limits the findings. For example, the largest trial randomized only 47 patients to laser. Furthermore, the analysis may have had inadequate power to detect small differences in the pooled effect on pain.

Conclusions: There is insufficient evidence to draw any firm conclusions regarding the use of laser for the treatment of osteoarthritis.

Low Back Pain

I. Randomized, double-blinded, placebo-controlled trial

- a. Basford conducted a trial evaluating the efficacy of a 1.06 μm , infrared, neodymium:yttrium-aluminum-garnet (Nd:YAG) laser with a 2.5 cm diameter in the treatment of musculoskeletal back pain. (Basford 1999)

Patients were block randomized with a computer-generated schedule to active or placebo treatment. Both groups were irradiated for 90 seconds at 4 equally spaced levels (a total of 8 points) along L2 to S3. The active laser group was irradiated with the probes emitting an average intensity of 542 mW/cm^2 . In contrast, the control group was irradiated with an inactive probe. Treatment occurred 3 times per week for 4 weeks.

Patients were evaluated based on Oswestry score, Schober test, changes in medication use, activity level, perception of benefit, and pain on a 100 mm VAS. Evaluation occurred at treatment midpoint, at the end of 12 sessions, and at 28 to 35 days.

Including 30 subjects per group had adequate power to detect a treatment effect.

Study Population: The study included 63 patients with nonradiating LBP of more than 30 days duration.

Patients were excluded due to litigation or workers' compensation, surgery, treatment in the last 30 days, radicular pain, or changes in bowel or bladder function.

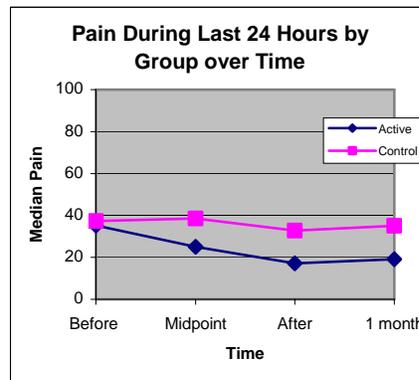
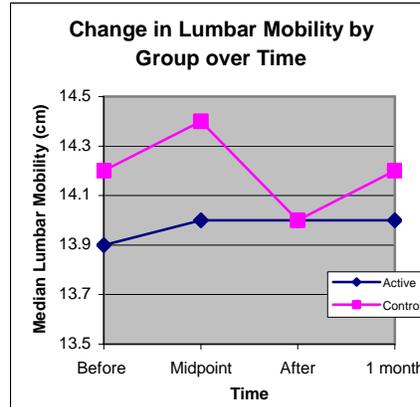
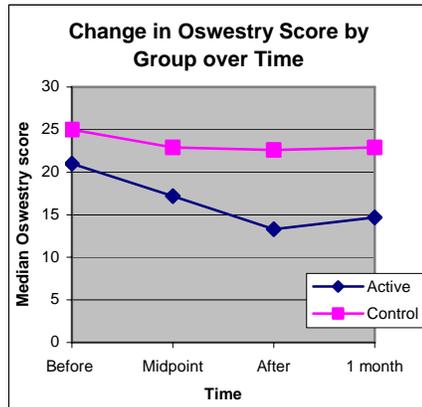
Of the 63 evaluated patients, 59 patients completed 11 of 12 treatments and were included in midpoint and follow-up analysis. 56 patients (27 active, 29 control) returned at 1 month.

	Active	Control
Number of Subjects	30	29
Age	47.8 years	48.2 years
Mean symptom duration	6.9 months	12.8 months
Median symptom duration	4.5 months	6.5 months
Analgesic use (no/day)	4.6	4.4

Results: The active laser group reported significant improvement in perception of treatment benefit and Oswestry compared with controls. Improvement in pain and function were modest and lessened over time.

The study did not detect differences between groups in lumbar mobility, tenderness to palpation, or pain with bending or straightening. Orthotic and analgesic use did not vary between groups.

Musculoskeletal Disorders – low back pain



Conclusion: Treatment with low-intensity 1.05 μm laser irradiation produced a moderate reduction in pain and improvement in function in patients with musculoskeletal LBP. Benefits were limited and decreased with time.

II. Randomized, observer-blinded, controlled trial

- a. Gur conducted a study of GaAs laser comparing LLLT, exercise, and LLLT combined with exercise to determine whether LLLT is useful for chronic LBP. Application was over a series of standardized fields that included the L4 to L6 and L5 to S1 apophyseal capsules, dorsolumbar fascia, interspinous ligaments, gluteal fascia, posterior sacroiliac ligaments, hamstrings, and gastro-soleus muscles. (Gur 2003)

Each point received 4 minutes of stimulation for a total stimulation time of 30 minutes. LLLT was applied 5 times a week for 4 weeks. The laser produced energy of approximately 1 J/cm^2 (10.1 cm^2 energy density, 2.1 kHz pulse frequency, 10 W diode power, 4.2 mW average power).

A physiotherapist conducted the first exercise session, and patients continued the program at home. Patients exercised twice a day for a total of 40 sessions over 4

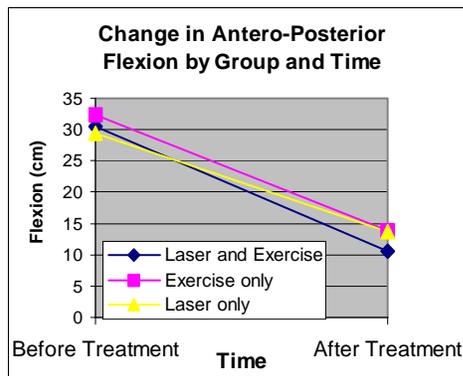
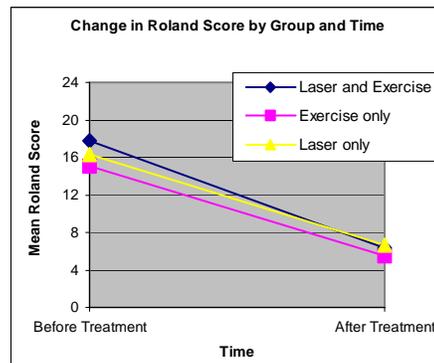
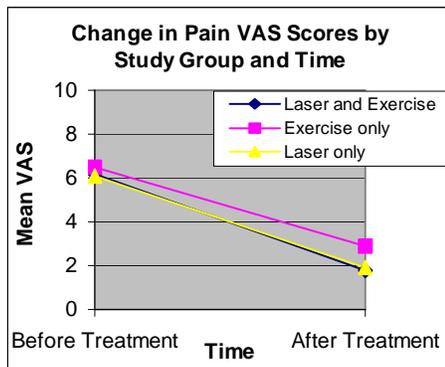
weeks. Exercises included lumbar flexion and extension, knee flexion, hip adduction exercises, and strength exercises.

The study measured outcomes with a VAS, Roland Disability, Modified Oswestry, Schober test, and flexion. One measure of a poor outcome was a Roland score of greater than 14.

Study Population: The study included 75 patients with chronic LBP for one year who had not undergone previous spinal surgery. Patients ranged in age from 20 to 50 years. Patients were excluded due to neurological deficits, or systemic or psychological illnesses.

Patients mean age was 35.6 years, and the mean duration of LBP was 14.6 months.

Results: Pain levels, Schober test scores, and antero-posterior flexion improved significantly after therapy in all groups. Pain levels in the laser plus exercise and laser alone groups decreased more than the exercise only group. However, the differences between groups were not significant.



Conclusion: LLLT may improve pain and functional disability in the therapy of chronic LBP, but it does not bring any additional benefits to exercise therapy.

Acute Ankle Sprains

I. Randomized, double-blind, placebo-controlled trial

- a. De Bie examined the effect of LLLT on acute lateral ankle sprains. LLLT acted as additional therapy to a standard treatment regimen of elastic wrapping for 4 days followed by 3.5 weeks of bracing and home exercises. (De Bie 1998)

Following stratification by injury severity and sports participation, a computer generated table randomized 217 patients to a treatment group.

	Low dose	High dose	Placebo
Number of patients	74	72	71
Energy at skin level	.5 J/cm ²	5 J/cm ²	0 J/cm ²
Energy at tissue level	0.07 J/cm ²	.7 J/cm ²	0 J/cm ²

The most painful area received 200 seconds of irradiation with a 904 nm wavelength laser at 25 W peak power. LLLT was administered 5 times in the first week, 3 times in the second week, and twice per week in the third and fourth weeks. The study also allowed 500 mg of Paracetamol every 4 hours.

The primary outcomes were pain on a 10-point VAS and function on a 100-point scale. Secondary outcomes were total days of sick leave, limitations in ADL, swelling, pressure, and threshold tests. Follow-up occurred at 4 weeks and 3, 6, 9, and 12 months.

The double-blinded study had adequate power and practiced intention to treat.

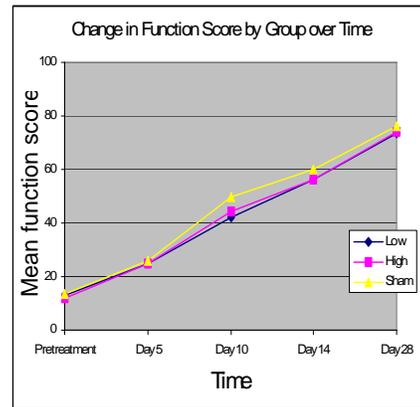
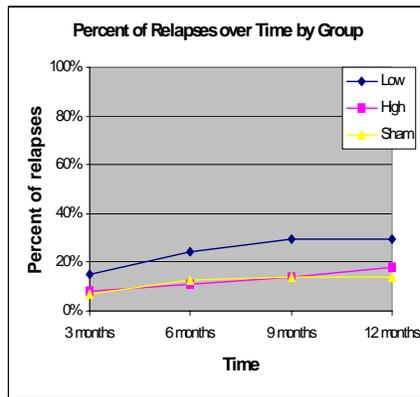
Study Population: The study included patients with acute lateral ankle sprains. Patients were excluded due to fracture, open trauma, underlying abnormality of foot and leg, or systemic disease.

	Low Dose	High Dose	Placebo
Mean Age	30.2	33.2	30.9
Blue/white collar ratio	37/35	37/30	35/32
Lost to follow-up	6 patients	3 patients	8 patients

Results: All study groups experienced pain improvement through Day 28, but the differences between groups were not significant. The outcomes that reached significance in the short term favored placebo: days of sick leave, hindrance in ADL on day 10, pressure pain on anterior talofibular ligament on day 14, and subjective recovery. No other measurements reached significance.

At one year, the study detected a significant difference in total days of sick leave in favor of placebo. There were no significant differences between groups on any other measure at 3, 6, 9, or 12 month follow-up.

Musculoskeletal Disorders – ankle sprains



Conclusion: The researchers conclude that LLLT is not an effective treatment of ankle sprains.

WOUND HEALING

Venous ulcer

Leg ulcers are associated with venous insufficiency and increased hydrostatic pressure in the veins of the leg. The standard therapy of applying external compression attempts to treat venous leg ulcers. Compression is intended to reverse venous insufficiency by aiding venous return. (Flemming 2004)

I. Systematic review and meta-analyses

- a. Flemming conducted a meta-analysis to examine the results of studies that evaluated LLLT for the treatment of wounds. The analysis included randomized trials published through June 1998 in any language. Study populations were comprised of patients with venous leg ulcers. (Flemming 2004)

Results: The 4 identified trials had small patient populations ranging from 15 to 23 subjects. Flemming classified the trials according to laser type:

- 2 HeNe laser studies - Bihari and Mester (1989) and Lundenberg and Malm (1991) utilized active laser at 4 J/ cm².
- 1 GaAs laser study - Malm and Lundenberg (1991) randomized 42 patients to laser at 1.96 J/ cm² or sham. All patients received standard treatment and exercise.
- 1 unspecified laser source study - Crous and Malherbe (1988) compared lasers to ultraviolet therapy.

Power, wavelength, frequency, duration, and follow-up treatment were different between all the studies.

Lundenberg showed that 4/23 (17%) ulcers healed in the intervention group compared to 3/23 (13%) ulcers in the sham group (RR 1.33). Malm showed that 13/21 (62%) ulcers healed in the intervention group compared with 11/21 (52%) ulcers in the sham group (RR 1.18). After pooling results, the analysis did not detect significant differences in ulcer healing between active and sham laser (RR 1.21).

Bihari compared laser alone, laser with infrared light, and non-coherent red light. Significantly more ulcers 12/15 (80%) healed in the combined laser and infrared light group compared to the non-coherent red light group (5/15, 33%) at 9 months. Crous showed no significant differences in healing between patients who received laser and ultraviolet light. The small trial included 3 patients per study group.

Conclusion: The analysis did not find sufficient evidence for or against LLLT in the healing of venous leg ulcers. There was not clear evidence as the trials were small and of poor quality.

- b. Schneider conducted a systematic literature review that identified additional studies supplementing the Flemming meta-analysis. The identified trials were published between 1993 and 1999 and included 2 randomized controlled clinical trials, 1 controlled clinical trial, 2 non-controlled clinical trials, and 1 prospective comparative study. (Schneider 1999)

Shuttleworth and Banfield did not specify the laser type or dressings used in the study making comparison with other studies difficult. The authors suggest that improvement in the control group resulted from promotion of desired outcome through inclusion in the study.

The Landau study compared LLLT combined with topical oxygen to topical oxygen therapy alone. However the study did not include comparison with conventional therapy.

The study by Gupta utilized a randomized, double-blind, placebo-controlled design. However, the patient numbers were very small.

Conclusion: The systematic review indicated that the scientific literature reported weak evidence concerning the ability of LLLT to accelerate wound healing. Therefore, the efficacy of LLLT for wound healing was not established, and scientific evidence did not support its use.

II. Randomized double-blind, placebo-controlled trials

- a. Franek evaluated the effect of LLLT on crural ulceration healing. All patients received topical baths of potassium permanganate, wet dressings of 0.1% solution of copper sulphate, compresses with colistin, fibrolan, chloramphenicol, and gentamicin. An 810 nm wavelength, continuous wave, GaAlAs laser with average 65 mW output provided active LLLT. Patients received LLLT five times a week at an average dose of 4 J/ cm². (Franek 2002)

Patients randomized to:

	A: Compressive therapy, topical pharmacological treatment, and laser	B: Compressive therapy, topical pharmacological treatment, and placebo laser	C: Compressive therapy, topical pharmacological treatment
Number of patients	21	22	22
Mean age	65 years	66 years	66 years
Mean ulceration duration	41 months	30 months	51 months
Mean ulceration surface (cm ²)	15.8 cm ²	13.3 cm ²	16.2 cm ²
Mean treatment time	4.5 weeks	5 weeks	5 weeks

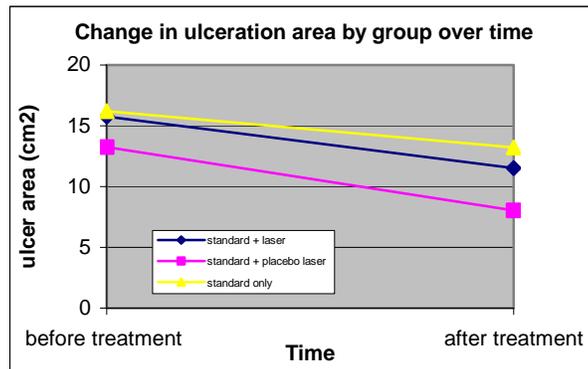
The study measured outcomes by monitoring the changes in the area of the defect. The values were used to calculate healing rate (average rate of change per week of

Wound healing – venous ulcers

the relative area and volume of the deficiency) and average rate of change per week of the relative suppurate area.

Study Population: The study included patients with chronic venous insufficiency. The ankle-brachial index in all patients was also equal or greater than 0.8. Patients were excluded due to ulcer related to an arterial component, diabetes, or vascular sclerosis.

Results: All groups experienced significant reduction in area and volume of the ulcers, but the study did not detect significant differences between groups. Group C showed a significant rate of change in suppurate area.



Conclusion: The study showed that laser stimulation did not have a significant impact on the healing of crural ulcers.

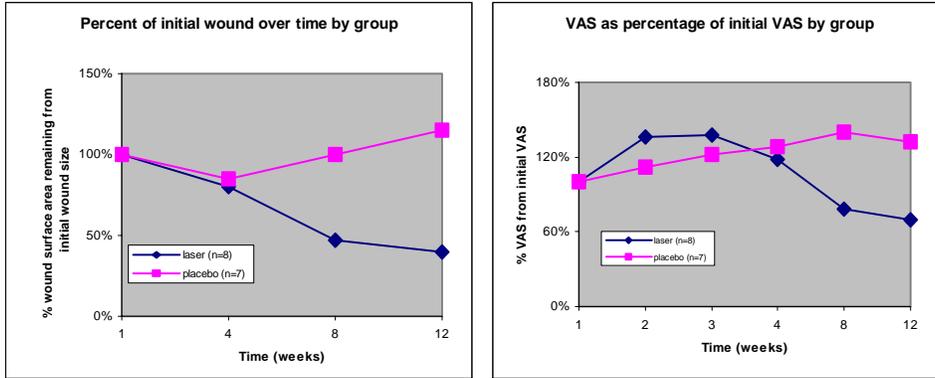
- b. Lagan's study compared active and placebo treatment of 16 chronic venous ulcers. All patients received wound cleansing, debridement, and application of dressings and/or compression bandage. The active, multi-wavelength (660-950 nm) treatment array delivered an average dose of 12 J/ cm². The GaAlAs laser had an average power output of 532 mW and pulse frequency of 5kHz. Treatment occurred once per week for 4 weeks. (Lagan 2002)

Wound area, wound appearance, and pain with a 10-point VAS were measured at 8 and 12 -week follow-up.

Study Population: The active treatment group (n=9) and the placebo group (n=7) had an average age of 69.9 years and a mean symptom duration of 11.3 months.

Results: Overall, results have indicated that, despite no statistically significant differences between groups, an apparent clinical difference in rate of wound healing was noted post-irradiation at follow-up. There were no statistically significant differences between groups for pain levels.

Wound healing – venous ulcers



Conclusion: The investigation demonstrated that there were no statistically significant differences in rates of wound healing or reduction in pain levels between active and placebo treatment.

Decubitus ulcer

A decubitus ulcer is also known as a pressure ulcer or pressure sore. These ulcers are defined as any degenerative change caused by pressure and shear forces acting upon tissues. There is no gold standard for treating decubitus ulcers. (Lucas 2003)

I. Randomized observer-blinded trial

- a. Lucas conducted a study in 3 nursing homes in The Netherlands. (Lucas 2003)
All patients were randomized to 1 of 2 treatment protocols:
 1. The control group received standard treatment comprised of patient instruction, wound cleansing, moist dressings, and frequent alteration of position. Patients underwent treatment daily for 6 weeks.
 2. The LLLT group received standard treatment and laser. LLLT was given 5 times a week.

LLLT was provided by a microprocessor-controlled, infrared, 904 nm wavelength GaAs-diode laser probe that irradiated a 12 cm² area for 125 seconds. The total peak power was 12 x 70 W in an 830 Hz pulse frequency mode of 150 ns pulses with an average beam power of 12 x 8 mW and a radiant exposure of 1 J/ cm².

The primary outcome was absolute (mm²) and relative (%) wound size reduction at 6 weeks compared to baseline.

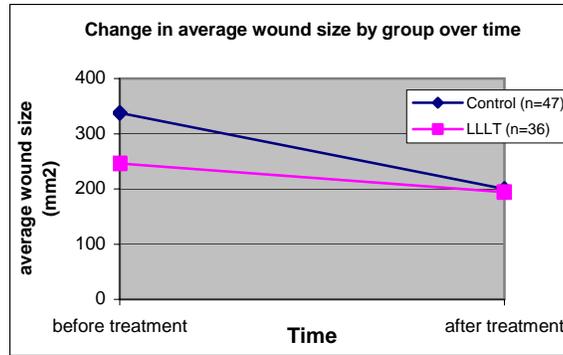
Assuming a 25% difference between groups, 80% power required 40 patients per group. The study practiced intention to treat.

Study Population: The study included patients with one Stage III decubitus ulcers, defined as a full thickness skin defect extending into the subcutaneous layers and adipose tissue. Patients were excluded due to wound size greater than 30 cm², wounds occluded by eschar, constant ulceration for over 1 year, or diabetes.

	control	LLLT
Number of patients	47	39
Mean age	83.5 years	81.3 years
Mean wound size	350 mm ²	317 mm ²
Ulcer duration	3.3 weeks	2.9 weeks
Loss to follow-up	3	2

Results: The study did not find any significant differences between groups on absolute improvement or relative improvement. Complete wound healing occurred in 15/47 (32%) of the control group compared to 18/39 (46%) of the LLLT group. Five control group patients and 3 LLLT patients developed a stage IV decubitus ulcer.

Wound healing – decubitus ulcers



Conclusion: The trial found no evidence justifying the use of LLLT as an adjuvant to standard decubitus ulcer treatment.

PAYMENT ISSUES

Insurers

Aetna's September 2003 policy states that cold laser therapy is experimental and investigational. There is inadequate evidence of the effectiveness of low-energy lasers in wound healing, pain relief, or for other musculoskeletal dysfunction, arthritis, and neurological dysfunction. (Aetna 2003)

Blue Cross of California and BlueCross BlueShield of Georgia determined in March 2004 that low-level laser for carpal tunnel is investigational. (Blue Cross 2004) (BCBS 2004)

The Regence Group determined in January 2004 that LLLT for neuromuscular pain was investigational. (Regence 2004)

General Motors offers LLLT to injured workers in its in-plant medical clinics. (Lindstrom 2004)

Costs

A recent article in *The Washington Post* reports that the laser device may cost approximately \$4000, while each treatment costs from \$25 to \$50 with a typical course of treatment involving 10 to 15 sessions over time. (Lindstrom 2004)

Weintraub estimates the cost of the laser treatment at \$133, including examination and nerve conduction velocity studies. (Weintraub 1997)

Codes

Codes 97039 and S8948 apply to LLLT.

Code	Description
97039	The application of a modality that requires direct (one-on-one) patient contact by the provider. Unlisted modality (specify type and time if constant attendance)
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low level laser; each 15 minutes

CONCLUSIONS

Low level laser therapy is a noninvasive treatment that has been used for many conditions. While researchers have published extensively on LLLT, the trials have generally been small, do not compare LLLT to alternative therapies, and apply a range of treatment parameters. In several trials, the placebo control groups have improved as much as active laser groups. Therefore, the evidence has not substantially shown the effectiveness of LLLT.

Carpal tunnel syndrome (CTS)

One laser manufacturer provided information concerning two randomized controlled trials of LLLT to treat CTS. While the studies suggest that active LLLT resulted in improvement more often than placebo, the effect was moderate. In addition, improvement did not extend to all measure outcomes. Loss to follow-up may have affected results, but the studies do not address attrition in their analyses.

Naerser's crossover trial of TENS and LLLT found improvement following active laser. However, the study population was small (n=11), and some key measurements were based on the results of only 8 patients. Therefore, the results of the study may not be generalizable to a larger population.

Two case series studies suggest that LLLT may be associated to improved pain and function. However, without a control or comparison group, the studies do not prove that LLLT directly results in improvement.

Due to the lack of published trials, LLLT for CTS is considered investigational.

Unspecified musculoskeletal disorders and tendinopathies

One meta-analysis on LLLT's effect on musculoskeletal pain found no effect of LLLT on pain compared to placebo. A second meta-analysis on LLLT's effect on tendinopathies found a pooled effect of 32% improvement in pain in favor of LLLT. A third meta-analysis on LLLT for chronic joint disorders showed a pooled improvement of approximately 30% in favor of active LLLT. However, the heterogeneity of the studies included in these meta-analyses substantially limits their findings. The included studies had varied treatment parameters, indications, and patient populations.

One randomized trial examined LLLT for soft tissue conditions. The study found greater improvement among placebo group patients. However, the number of indications included for treatment in the study limits the ability to draw conclusions from the results.

A recent trial on lateral epicondylitis was not included in any of the meta-analyses. The small trial (n=30) showed marginal benefit of active laser over placebo for patient perception of benefit and improved lifting ability.

Conclusions

While the pooled analyses concerning tendinopathy suggest a possible 30% effect, the heterogeneity of included studies limits these findings. Therefore, there is not substantial evidence to draw firm conclusions concerning the effectiveness of LLLT for general musculoskeletal disorders and tendinopathies.

Osteoarthritis

A meta-analysis of osteoarthritis was conducted of trials published through 2002. The trials were of moderate quality and did not find any treatment effect following LLLT compared to placebo. Therefore, the evidence does not substantially show LLLT effectiveness for osteoarthritis.

Low Back Pain

One double-blind trial showed that active laser resulted in greater perception of treatment benefit. While pain and function improved, the modest improvement lessened over time. The study did not detect differences in mobility or pain with movement.

One observer-blinded study showed that laser did not add benefit to exercise in the treatment of chronic low back pain.

Due to the moderate and inconsistent nature of the results, the evidence has not substantially shown LLLT's effectiveness for low back pain.

Ankle Sprains

One double-blind study did not find improvement on pain or function following active high or low dose laser compared to placebo. The researchers conclude that LLLT is not effective for ankle sprains.

Wound Healing

A meta-analysis included studies of LLLT for venous leg ulcers published through 1998. After pooling results, the analysis did not detect differences between active and sham laser in the treatment of venous leg ulcers.

Two recent double-blind trials not included in the meta-analysis compared standard therapy with active laser to standard therapy with sham laser. The studies did not detect differences in improvement between the treatment groups.

Pooled analyses concerning wound healing have not detected any improvement of active laser compared to placebo. The evidence has not shown LLLT to be effective in the treatment of venous wounds.

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