Potential Treatment for Cognitive Dysfunction using Transcranial Laser / Light Emitting Diodes

Margaret Naeser, Ph.D., L.Ac.

Neuroimaging in Aphasia, and Transcranial Magnetic Stimulation to Treat Aphasia
VA Boston Healthcare System

Harold Goodglass Boston University Aphasia Research Center
Department of Neurology
Boston University School of Medicine

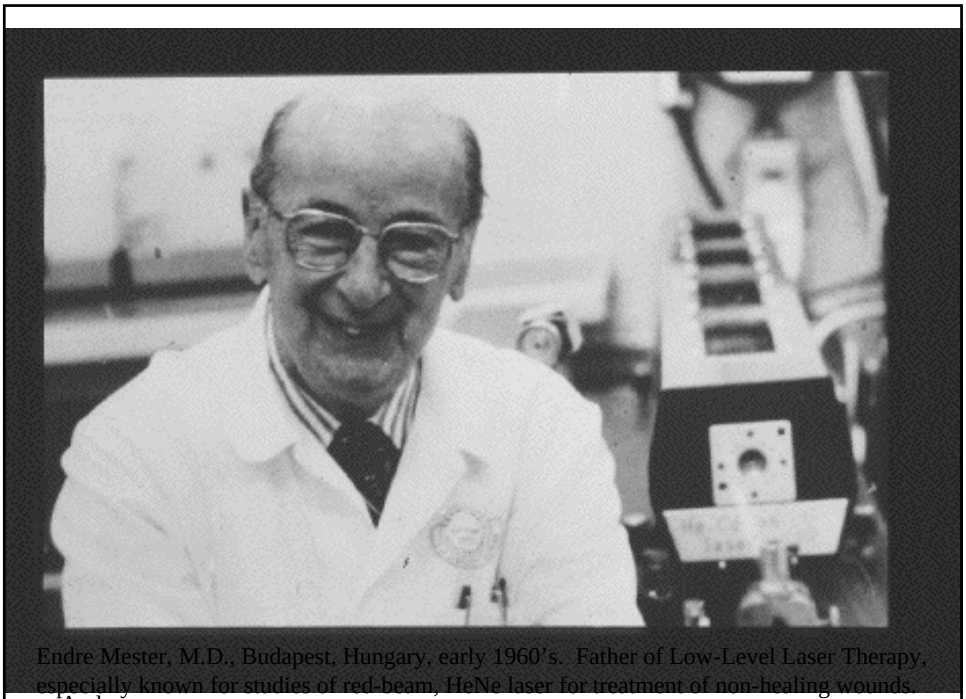
Four Parts to this Lecture

1. ***Laser Basics***, including some ***Cellular Effects***

2. ***Case Report***, Transcranial LEDs to Treat Cognitive Dysfunction in Chronic TBI

3. Previous Research: Low-Level Laser Therapy (Acupuncture) to treat
   Paralysis in stroke;
   and ***Pain in Carpal Tunnel Syndrome***

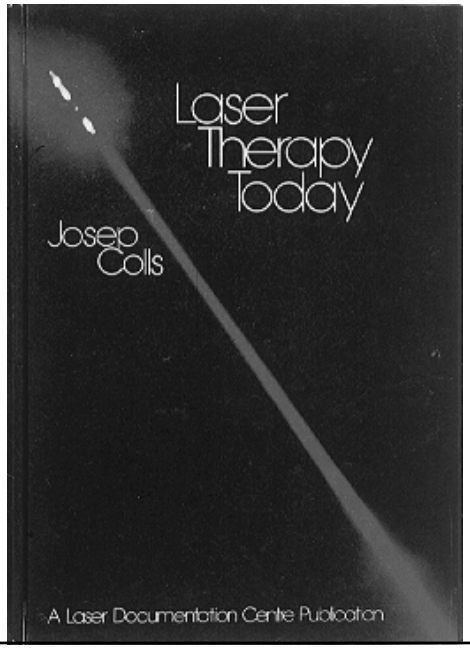
4. Two Studies where Low-Level Laser Therapy was used to treat ***Fibromyalgia***

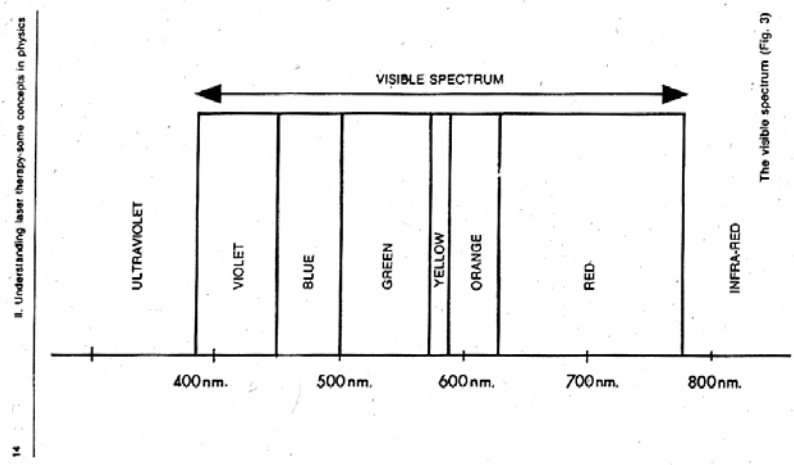


Endre Mester, M.D., Budapest, Hungary, early 1960's. Father of Low-Level Laser Therapy, especially known for studies of red-beam, HeNe laser for treatment of non-healing wounds.

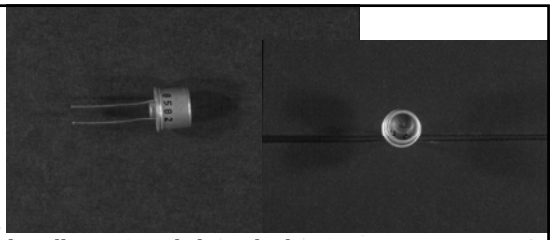
Andre

Part 1. Laser Basics

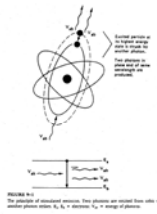




Source: Collis Cruanes J: Laser Therapy Today, Barcelona, Laser Documentation Center, S.A, Calle Dalmau 11 - 08014, 2nd Edition, November, 1985; ISBN 84-398-6137-0. Translated by Lucie Maguire



Sample gallium arsenide laser diode. Naeser Lecture Notes®



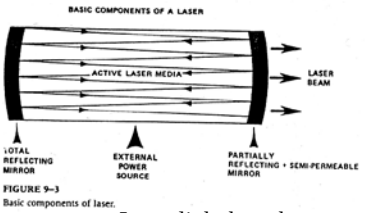


FIGURE 9–3
Basic components of laser.

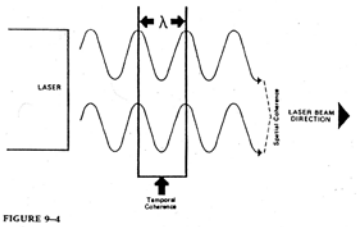
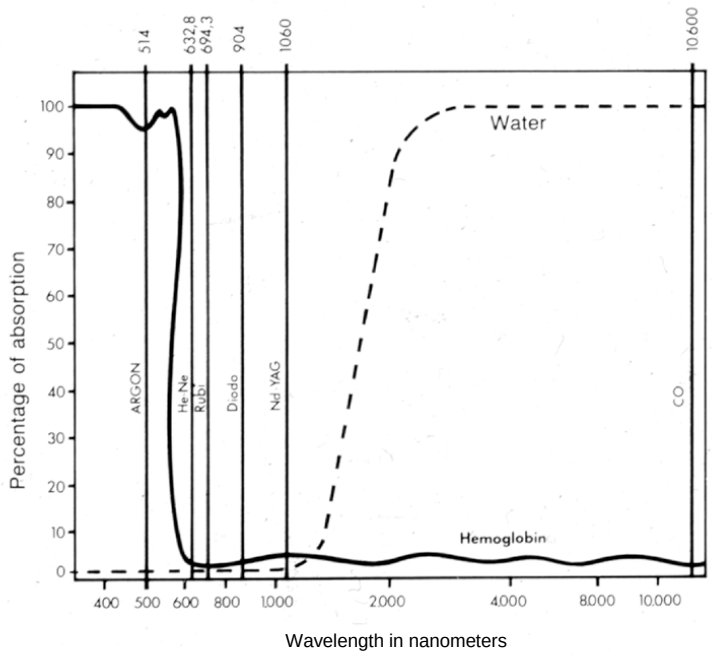


FIGURE 9–4
Coherence—The laser is highly coherent in temporal and spatial planes.

Laser light has photons that are monochromatic and coherent.

Source: Seitz LM, Kleinkort JA: Low-Power Laser: Its Applications in Physical Therapy. Chapter 9, in Thermal Agents in Rehabilitation. Michlovitz SL, Editor and Wolf SL, Editor-in-Chief. Philadelphia, F.A. Davis Co., 1986, pp. 217-238.



Colls Cruanes, Josep. Laser Therapy Today. Laser Therapy Documentation Center, Barcelona, 1986, p. 45

Laser Wavelengths (nm), and Depth of Laser Penetration

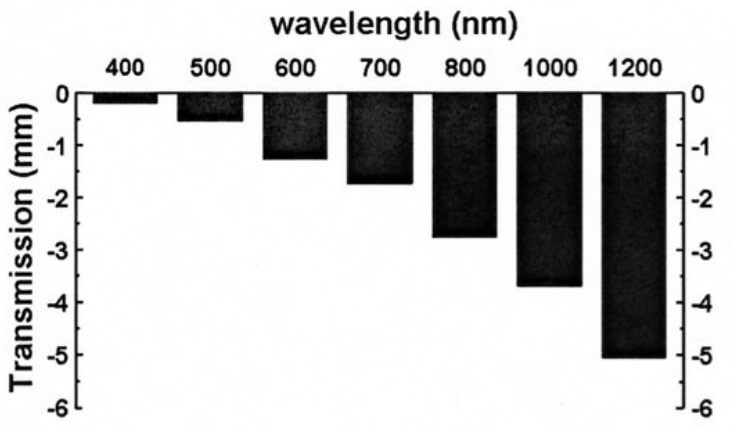
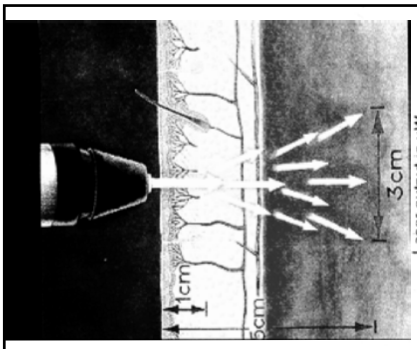
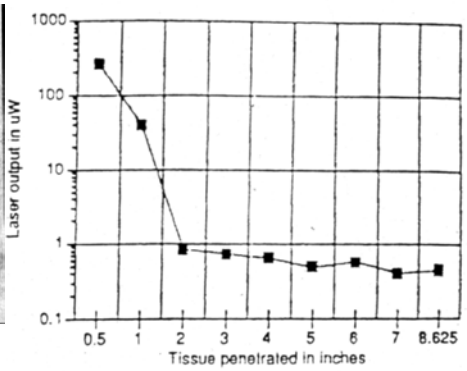


Fig. 1 Transmission in skin. Approximate skin transmission depth at which the incident radiant exposure has decreased by 90%. The transmission depth for a 99% decrease can be calculated by doubling the corresponding 90% depth. Data shown are for fair Caucasian skin. Graph drawn from data presented in [29]

Sources: Anderson RR & Parrish JA (1981); and Whittaker P. (2004).





Infrared laser, 904 nm
10 Watt peak power pulsed (3,500 pps), gallium arsenide diodes

Four laser diodes placed in a horizontal strip 5.6 cm long
Pulse width, 157 ns for pulses generated

Hudson DE. Preliminary study to measure laser light and LED penetration through tissue. Respond Systems (Branford, CT) Technical Report;1997:1-4.

How to Calculate the Number of Sec. Required to Produce 1 Joule of Energy

Three variables are listed below which you must know about a specific laser, before using it. You will also need to know the beam spot size in cm2, which is explained later.

1. The wavelength, in nanometers (nm, one billionth of a meter). For "laser acupuncture," the wavelength is usually in the red-to-infrared range of 600-1,000 nm. Otherwise, the hemoglobin or water may block the laser beam. The laser manufacturer supplies information on the nm wavelength for each laser.

2. The number of watts, or milliwatts (mw). Usually only 5 or 500 mw (always less than 500 mw). If the laser is greater than 500 mw, it will cause an "ouch" response, and will burn the skin. The laser manufacturer supplies information on the number of milliwatts for each laser.

3. The number of seconds exposure = 1 joule of energy (A "joule" is a unit of work energy - for example, the energy expended by a current of 1 ampere flowing for 1 second through a resistance of 1 ohm.)

Some low-level laser research or clinical papers are published showing only the number of Joules (J) used, per point on the skin. **It is better, however, to know treatment protocols in J/cm2, per point, or per cm2 on the skin,** as is explained on additional pages in this handout. When J/cm2 is calculated for a specific laser, the beam spot size must also be known (in cm2). It is important, however, to understand the basic concept of Joule, or unit of work energy.

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Energy Density Dosages (Joules/cm^2) for Various Treatment Effects

- Analgesic effect: Muscular pain ---------- 2 to 4 joules/cm^2
  Joint pain ---------- 4 to 8 joules/cm^2
- Anti-inflammatory effect: Acute and subacute 1 to 6 joules/cm^2
  Chronic---------- 4 to 8 joules/cm^2
- Eutrophic effect: ---------- 3 to 6 joules/cm^2
- Circulatory effect:---------- 1 to 3 joules/cm^2

Colls Cruanes, Josep. Laser Therapy Today. Laser Therapy Documentation Center, Barcelona, 1986, p. 72.

For a 5 mW laser, it takes 200 Sec. to produce 1 Joule of energy.

Why beam spot size, cm^2, is important: 

	1 Joule = 200 Sec	1 Joule = 200 Sec	1 Joule = 200 Sec
Laser Aperture *Diameter*	*1.14 cm*	*.5 cm*	*.1 cm*
Radius	.57	.25	.05
Beam Spot Size: š (3.14) x r^2	1.02 cm^2	0.196 cm^2	0.0078 cm^2
1 J/cm^2 = cm^2 / W	1.02 cm^2 / .005	0.196 cm^2 / .005	0.0078 cm^2 / .005
1 J/cm^2	204 Sec	39.2 Sec	1.56 Sec
Used for 200 Sec.	200/204 = .98 J/cm^2	200/39.2 = 5.1 J/cm^2	200/1.56 = 128.2 J/cm^2

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For a 500 mW laser, it takes 2 Sec. to produce 1 Joule of energy.

Why beam spot size, cm^2, is important: 

	1 Joule = 2 Sec	1 Joule = 2 Sec	1 Joule = 2 Sec
Laser Aperture			
Diameter	***1.14 cm***	***.5 cm***	***.1 cm***
Radius	**.57**	**.25**	**.05**
Beam Spot Size:	**1.02 cm^2**	**0.196 cm^2**	**0.0078 cm^2**
š (3.14) x r^2			
1 J/cm^2 = cm^2 / W	**1.02 cm^2 / .500**	**0.196 cm^2 / .500**	**0.0078 cm^2 / .500**
1 J/cm^2	**2.04 Sec**	**.392 Sec**	**.0156 Sec**
Used for 2 Sec.	**2/2.04 = .98 J/cm^2**	**2/.392 = 5.1 J/cm^2**	**2/.0156 = 128.2 J/cm^2**

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Nonsignificant Risk Device Studies:

- Biostimulation Lasers for treatment of pain
- Caries Removal Solution
- Daily Wear Contact Lenses and Associated Cleaners & Solutions
- Dental Filling Materials, Cushions or Pads made from traditional materials and designs
- Denture Repair Kits and Realiners
- Gynecologic Laparoscope and Accessories at power levels established prior to May 28, 1976 (excluding use in female sterilization)
- Externally Worn Monitor for Insulin Reactions
- Jaundice Monitor for Infants
- Magnetic Resonance Imaging (MRI) Devices within specified physical parameters
- Menstrual Pads
- Menstrual Tampons of "old" materials (used prior to May 28, 1976)
- Nonimplantable Male Reproductive Aids
- Ob/Gyn Diagnostic Ultrasound (within specified parameters)
- Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain.
- Wound Dressings, excluding absorbable hemostatic devices and dressings

Significant Risk Device Studies:

GENERAL MEDICAL USE

- Catheters: Cardiology - diagnostic, treatment, transluminal coronary angiolplasty, intra-aortic balloon with control system
  Gastroenterology and Urology - biliary and urologic
  General Hospital - long-term percutaneous, implanted, subcutaneous and intravascular
  Neurology - cerebrovascular, occlusion balloon
- Collagen Implant Material for use in ear, nose and throat, orthopedics and plastic surgery
- Lasers for use in Ob/Gyn, cardiology, gastroenterology, urology, pulmonarnesthesia Apparatus
- Gas Machines for anesthesia or analgesia
- High Frequency Jet Ventilators greater than 150 BPM

CARDIOVASCULAR

- Arterial Embolization Device
- Artificial Heart, permanent implant and short term use
- Cardiac Bypass Systems: oxygenator, cardiopulmonary blood pump, ventricular assist devices
- Cardiac Pacemaker/Pulse Generator: implantable, external transcutaneous, antitachycardia, esophageal

Guidance on Significant and Nonsignificant Risk Device Studies.
Prepared by: Office of Device Evaluation, Center for Devices and Radiological Health, FDA, June, 1986

Table 1. Cellular Effects of Low-Energy Laser Irradiation (Basford, 1989)

Phenomenon	Change and reported	Model	Laser
Collagen and protein synthesis Glassberg, Lask, Litto, 1968 Simunovic, Ivankovich, 1968 Barabas, Bakos, Szabo, et al, 1968 Mester, Toth, Mester, 1982 Lyons, Abergel, White, Dwyer, Castel, Litto, 1987 Hermah, Khosla, 1987	Increase & decrease	Human fibroblasts, rabbit skin, human synovium, bovine cartilage	HeNe HeNe + GaAs Nd:PO_4 glass Nd:YAG
RNA synthesis Glassberg, Lask, Litto, 1968 Simunovic, Ivankovich, 1968 Barabas, Bakos, Szabo, et al, 1968 Mester, Toth, Mester, 1982 Lyons, Abergel, White, Dwyer, Castel, Litto, 1987 Herman, Khosla, 1987 Karu, 1987	Increase	Mouse skin	HeNe
Cell proliferation Hardy, Hardy, Fine, Sokal, 1967 Abergel, Dwyer, Meeker, Iask, Kelly, Litto, 1984	Increase & decrease	Mouse fibroblasts, human lymphocytes	Ruby HeNe GaAs
Cell granule release Trelles, Mayayo, Miro, Rigau, Baudin, 1988	Increase	Mouse mast cells	HeNe
Cell Motility Sato, Landthaler, Haina, Schill, 1984	Increase	Human sperm	Kr
Membrane potential Passarella, Casamassima, Molinari, Pastore, Quagliariello, Catalano, Cingolani, 1984 Passarella, 1988 Kubasova, Kovacs, Somosy, Unik, Kokai, 1984	Increase	Rat liver mitochondria, human fibroblasts	HeNe
Cell binding affinities Kubasova, Kovacs, Somosy, Unik, Kokai, 1984 Passarella, Casamassima, Quagliariello, Caretto, Jirillo, 1985	Increase	Human lymphocytes and fibroblasts	HeNe
Neurotransmitter release Vizi, Mester, Tizta, Mester, 1977 Oxyhemoglobin dissociation Itzkan, Tang, Bourgelais, 1988	Increase Increase	Acetylcholine (guinea pigs)	Ruby
Phagocytosis Mester, Mester, Mester, 1985	Increase	Human leukocytes	Ruby
ATP syntheses Passarella, Casamassima, Molinari, Pastore, Quagliariello, Catalano, Cingolani, 1984 Passarella, 1988	Increase	Rat liver mitochondria	HeNe
Intercellular matrix Yew, Wong, Chang, 1982	Increase	Mouse retina	HeNe
Prostaglandin synthesis Mester, Toth, Mester, 1982	Increase	Rat skin	HeNe

Neuroscience Letters, 43 (1983) 339–344
Elsevier Scientific Publishers Ireland Ltd.

RELIEF FROM CHRONIC PAIN BY LOW POWER LASER IRRADIATION

J. WALKER

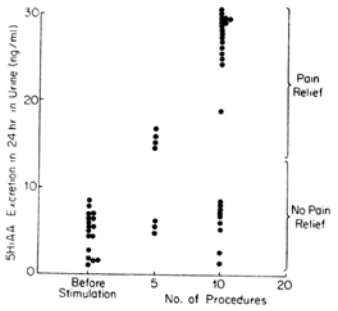
The Pain Institute, 1964 Westwood Boulevard, Suite 220, Los Angeles, CA 90025 (U.S.A.)

(Received September 5th, 1983; Revised version received October 13th, 1983; Accepted October 17th, 1983)

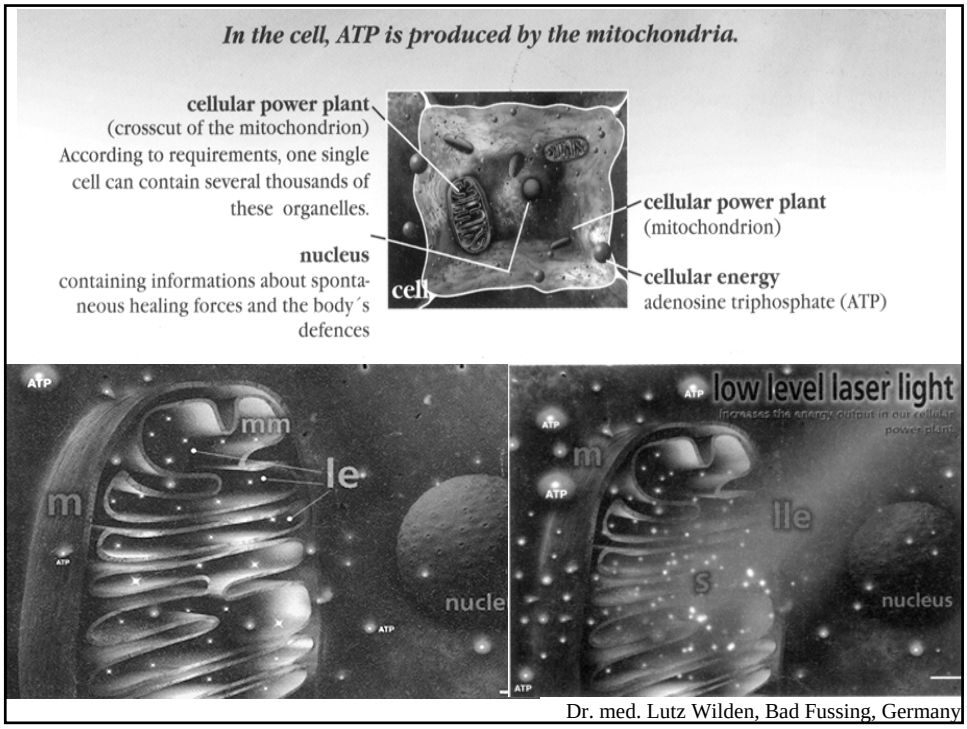
Key words: chronic pain – serotonin metabolism – helium-neon laser – 5-hydroxyindoleacetic acid

SUBJECTS EXPERIENCING PAIN RELIEF AS A RESULT OF LASER TREATMENT

Experimental	n	No. of years of pain	No. experiencing pain relief	% Estimated pain relief
Trigeminal neuralgia	9	12 ± 5	7	85 ± 7
Post-herpetic neuralgia	5	4 ± 2	2	60 ± 10
Osteoarthritis	5	10 ± 2	4	70 ± 3
Radiculopathy (sciatica)	6	4 ± 1	5	70 ± 5
Diabetic neuropathy	1	3	1	82
	26		19	
Control				
Trigeminal neuralgia	3	10 ± 5	0	10 ± 3
Post-herpetic neuralgia	2	4 ± 1	0	8 ± 5
Osteoarthritis	3	11 ± 3	0	7 ± 2
Sciatica	2	3 ± 1	1	12 ± 5
	10		01	



A 6 month follow-up of the patients indicated that 15 of the 19 originally pain-free patients were pain-free via pain estimate scale [8, 9] without additional treatment. Analgesic use was virtually eliminated. Confirmation of these results is under-



Dr. med. Lutz Wilden, Bad Fussing, Germany

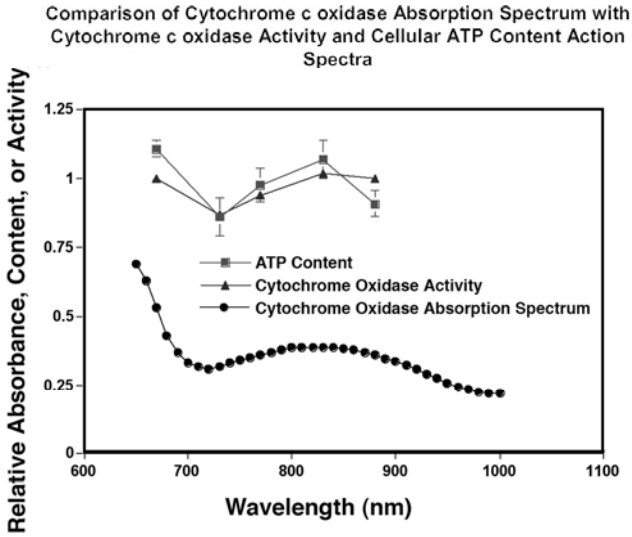
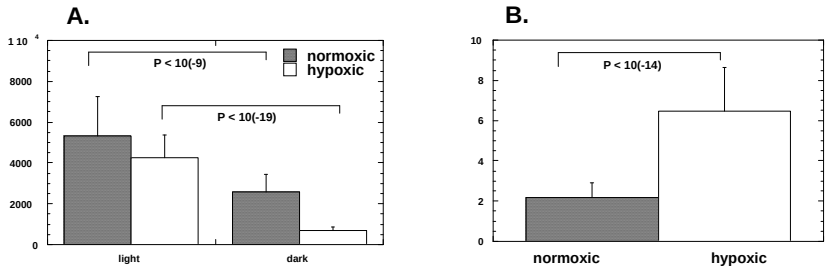


FIG. 8. **Action and absorption spectra in the far red and near infrared range for oxidized cytochrome *c oxidase (15), relative* cytochrome *c oxidase activity, and relative ATP content in TTX-treated neurons exposed to LED treatments at different wavelengths* expressed as percentages of controls (present study). Note the correspondence of effective wavelengths (especially 670 and 830 nm)** with the absorption spectrum of oxidized cytochrome *c oxidase and the non-correspondence of the least effective wavelength (728 nm).*

Wong-Riley et al., J. Biological Chemistry, 2005

Low-Level Laser Therapy (LLLT), 1.4 J/cm^2 of 810 nm IR light delivered at 10 mW/cm^2 has bigger effect in increasing ATP **in hypoxic cells** (1 hour under N_2)

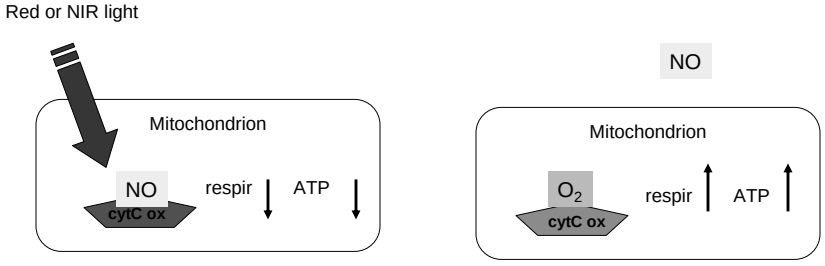


A. Mean luminescence values (+/- SD) from 12 wells of HeLa cells (a human cervical cancer cell line often used to demonstrate LLLT effects) **treated or not with 1.4 J/cm2 of 810 nm light in either normoxic conditons (regular atmosphere) or hypoxic conditions (1 hour exposure to pure nitrogen after 3 cycles of vacuum).**

B. Ratio of ATP in illuminated, compared to dark wells, as described in A.

Michael Hamblin, Ph.D., R.Rox Anderson, M.D., Wellman Center for Photomedicine, Massachusetts General Hospital, Boston, MA

Effect of red or near IR light on cellular respiration, oxygenation

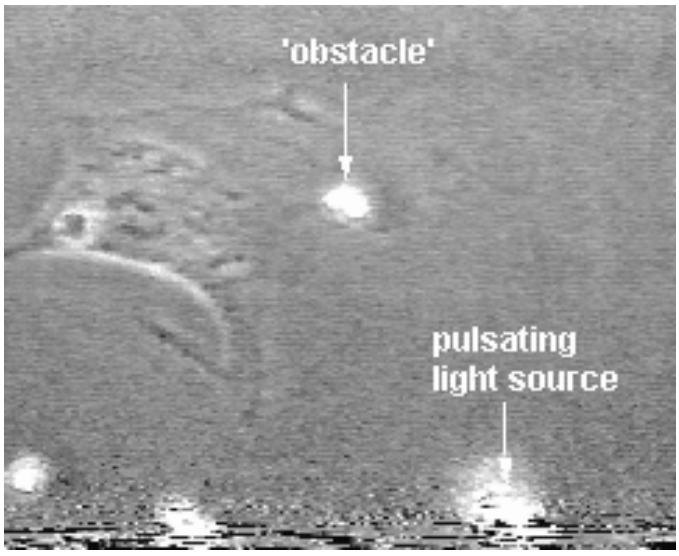


Explains why:
Normal cells and tissue generally do not respond
Hypoxic cells, damaged cells, and tissue at risk of death respond well
Effects continue for long time after light is switched off
Released nitric oxide temporarily increases blood flow in illuminated area
Released nitric oxide reduces swelling by dilating lymphatics and increasing drainage

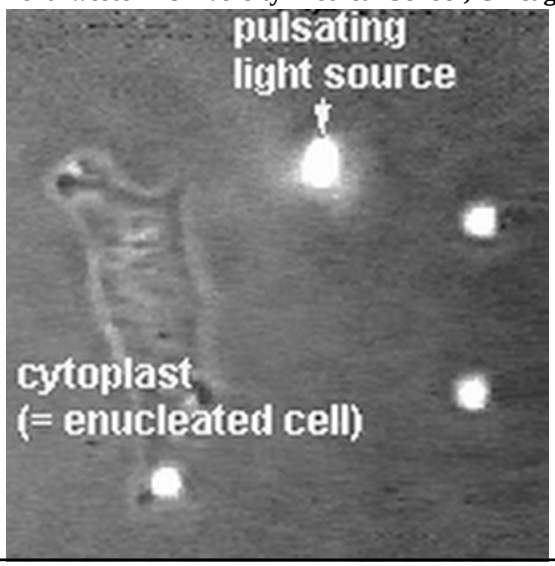
Michael Hamblin, Ph.D., R.Rox Anderson, M.D., Wellman Center for Photomedicine, Massachusetts General Hospital, Boston, MA

Video of a mouse fibroblast cell, seeking out a pulsating near IR laser light.
Source: Guenter Albrecht-Buehler, Ph.D., Physicist
Northwestern University Medical School, Chicago

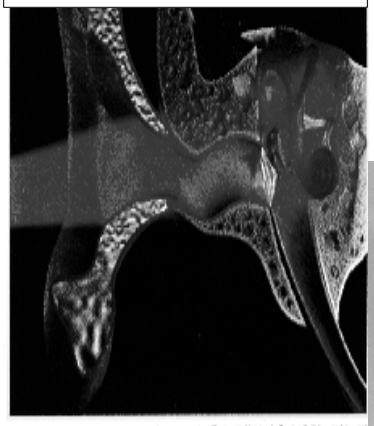
Video of a mouse fibroblast cell, seeking out a pulsating near IR laser light.
Note, *the cell maneuvers around an obstacle*, to get to the laser light.
Source: Guenter Albrecht-Buehler, Ph.D., Physicist
Northwestern University Medical School, Chicago



Video of a mouse fibroblast cell, seeking out a pulsating near IR laser light.
The nucleus has been removed from this cell (an enucleated cell), yet the remainder of the cell still seeks out the light - the mitochondria are outside the nucleus.
Source: Guenter Albrecht-Buehler, Ph.D., Physicist
Northwestern University Medical School, Chicago

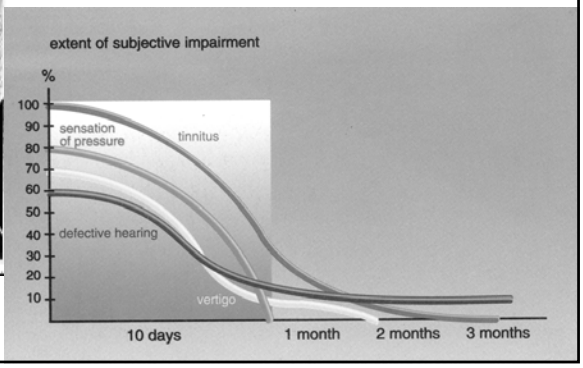


low level laser light in the auditory canal, middle, and inner ear



Some of the photons from laser or LEDs will penetrate through bone, probably because bone has a crystalline structure.

Data and Figures from:
Dr. med. Lutz Wilden, Bad Fussing, Germany



Part 2: Transcranial, High-intensity, LED Therapy to Treat Cognitive Dysfunction in *Chronic*, Mild Traumatic Brain Injury: Case Report

Margaret Naeser, PhD, LAc [1]
Anita Saltmarche, RN, MHSc[2]

Paper presented at the No. Am. Assoc. for Laser Therapy (NAALT) Meetings, San Francisco, June 13, 2009

[1] VA Boston Healthcare System
and Department of Neurology, Boston University School of Medicine

Neuroimaging (fMRI and DTI) in Stroke Patients with Aphasia and Transcranial Magnetic Stimulation (TMS) to Treat Aphasia
Harold Goodglass Boston University Aphasia Research Center

[2] VP Clinical & Scientific Affairs, MedXHealth Corp., Toronto, Canada

Naeser & Saltmarche, NAALT, 2009

Recent studies have reported

a single, *transcranial*, low-level laser therapy (LLLT) treatment

to have a *significant, beneficial effect* when used to treat acute stroke in humans.

Lampl, Zivin, Fisher, et al., *Stroke*, 2007

Zivin, Albers, Bornstein, et al., *Stroke*, 2009

Naeser & Saltmarche, NAALT, 2009

Transcranial, Laser Therapy Protocol with Acute, Human Stroke Patients:
(Lampl, et al., *Stroke*, 2007)
Treated only once, about 18 hours post-stroke (non-hemorrhagic, no tPA)

NeuroThera Laser System (NTS), PhotoThera Laser Co., San Diego, CA
Class IV Laser (>500 mW), 808 nm, near-infrared
Shaved all hair off of the head, of the stroke patient.
Trained operator placed the handheld device for 2 minutes on 20 points all all over the head, *both hemispheres*, regardless of side of stroke.
Energy Dose to the Brain Cortex* estimated to be only *1 Joule/cm²
Sham device used on 1/3 of the patients. No perceptible heat, Real or Sham

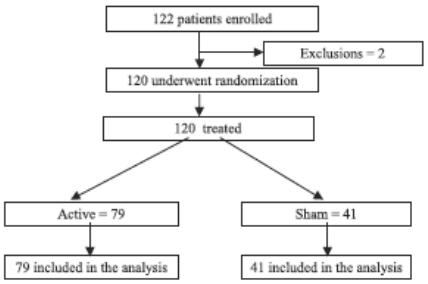


Figure 1. Disposition of patients in the study.

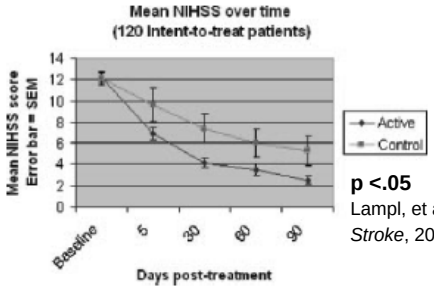


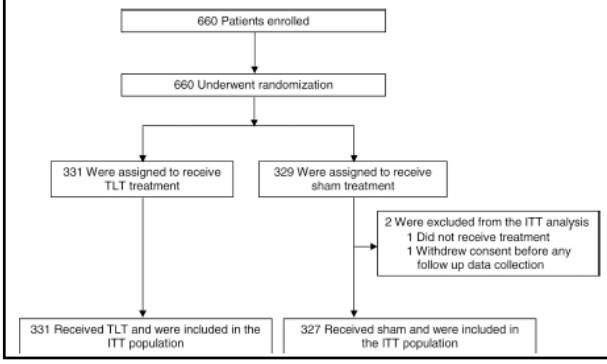
Figure 2. Mean NIHSS over time for each treatment group.

p <.05
Lampl, et al., *Stroke*, 2007

Naeser & Saltmarche, NAALT, 2009

Transcranial, Laser Therapy Protocol with Acute, Human Stroke Patients:
(Zivin, et al., *Stroke*, 2009)
Treated only once, < 24 hours post-stroke (non-hemorrhagic, no tPA)

NeuroThera Laser System (NTS), PhotoThera Laser Co., San Diego, CA
Class IV Laser (>500 mW), 808 nm, near-infrared
Shaved all hair off of the head, of the stroke patient.
Trained operator placed the handheld device for 2 minutes on 20 points all all over the head, *both hemispheres*, regardless of side of stroke.
Energy Dose to the Brain Cortex* estimated to be *only 1 Joule/cm²
Sham device used on 1/2 of the patients. No perceptible heat, Real or Sham



Significant (p = .04), beneficial results only in patients receiving Real (vs. Sham) with NIH Stroke Severity scores of *Moderate to Moderate-Severe,* at Baseline entry.

Naeser & Saltmarche, NAALT, 2009

Conclusions from two, transcranial LLLT studies with human stroke patients:

Transcranial, laser therapy in human stroke patients was *safe*.

Possible mechanisms of action included

- **Stimulation of mitochondria**
- **Increase in ATP production**
- **Mitigation of apoptosis**
- **Possible enhancement of neurorecovery mechanisms.**

Lampl, Zivin, Fisher, et al. *Stroke*, 2007; Zivin, Albers, Bornstein, et al. *Stroke*, 2009

Naeser & Saltmarche, NAALT, 2009

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DOI: 10.1089/neu.2006.0198

Low-Level Laser Therapy Applied Transcranially to Mice following Traumatic Brain Injury Significantly Reduces Long-Term Neurological Deficits

AMIR ORON,[1] URI ORON,[2] JACKSON STREETER,[2] LUIS DE TABOADA,[2] ALEXANDER ALEXANDROVICH,[3] VICTORIA TREMBOVLER,[3] and ESTHER SHOHAMI[3]

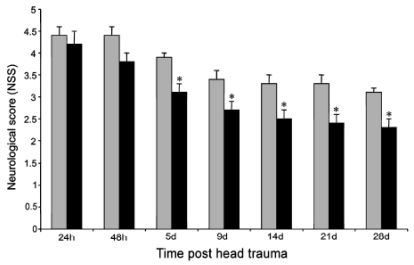

FIG 1. Neurological score (NSS) of control/non-laser-treated (gray columns) and laser-irradiated (black columns) mice at different time intervals after induction of brain trauma. Results are expressed as mean ± SD. *Statistical significance level is $p < 0.05$.

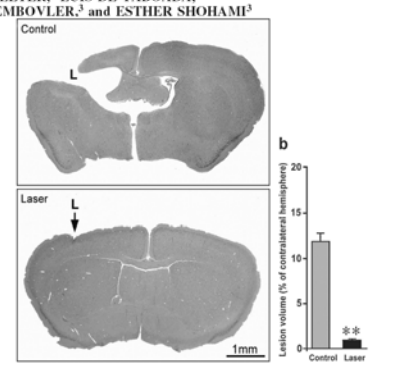

FIG 2. (a) Representative micrographs of cross-sections of control non-laser-treated and laser-treated mice brains. (b) Lesion volume of control (gray column) and laser-treated (black column) traumatized brains 28 days after induction of head trauma. Note lesion (L) in the control as compared to minimal lesion (arrow) in the laser-treated brain. Scale bar = 5 mm. $^{**}p < 0.01$.

Naeser & Saltmarche, NAALT, 2009

Traumatic Brain Injury (TBI)

- Significant socio-economic burden in the U.S.

- 80,000 to 90,000 individuals sustain long-term disabilities annually. (Thurman et al., 1999)

- With closed-head TBI, *diffuse axonal injury (DAI)* is one of the main consequences. These injuries result when shearing, stretching, and/or angular forces pull on axons and small vessels. Normal structural CT or MRI scan.

Taber, Warden, Hurley, 2006; Medana, Esiri, 2003

Naeser & Saltmarche, NAALT, 2009

Traumatic Brain Injury (TBI)
Often results in Cognitive Dysfunction

- Chronic, mild TBI (mTBI) is associated with *persistent* post-concussive symptoms, and problems with:
- attention
- cognitive manipulation of temporal information
- processing speed
- *working memory,* i.e., the ability to hold information in mind, and to manipulate it in light of incoming material.

- These "Executive Functions" are sensitive to damage of frontal lobe - orbital, medial (anterior cingulate), and dorsolateral, prefrontal cortex. Naeser & Saltmarche, NAALT, 2009

Functional Brain Imaging (PET) Study in Chronic ,TBI

Kato et al., *J. of Neurotrauma*, 2007

***Significantly low*, regional glucose metabolism (rCM) observed in 36 chronic TBI cases, DAI; mean age=36.3 Yr., SD=9.8; at 6-38 months post- motor vehicle accident (MVA), compared to normal controls.**

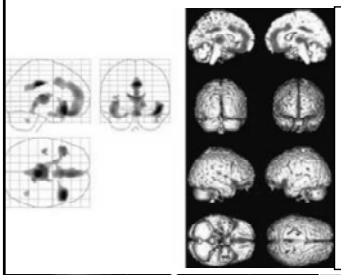

Fig. 1. Brain PET studies during resting state, with chronic TBI cases (> 6 months post-TBI) (Kato et al, 2007).
(Left) Regions of decreased cerebral metabolism ($p<0.001$) in TBI group compared with normal controls are displayed on a glass brain.
(Right) Red areas show decreased cerebral metabolism in *bilateral medial prefrontal cortex* (top row, white arrows), as well as other areas, including anterior superior temporal gyrus (bottom rows) during resting PET scans.

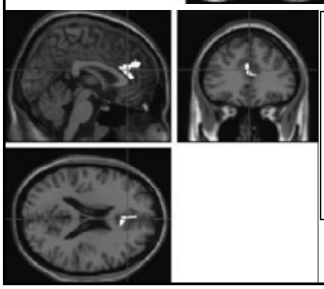

Fig 2. Solid white areas, in bilateral, medial prefrontal cortex and ant. cingulate gyrus mark the location of significant ($p<0.01$) positive correlation with Full-Scale IQ, and regional cerebral metabolism for these cortical areas in the chronic TBI cases. Results for regression analysis for Full-Scale IQ and cerebral metabolism in the TBI patients are superimposed on a normal magnetic resonance imaging (MRI) template (Kato et al, 2007).

Naeser & Saltmarche, NAALT, 2009

FRONTAL HYPOACTIVATION IN WORKING MEMORY AFTER DIFFUSE TBI

Functional MRI Study with Chronic, Traumatic Brain Injury (TBI) Cases.

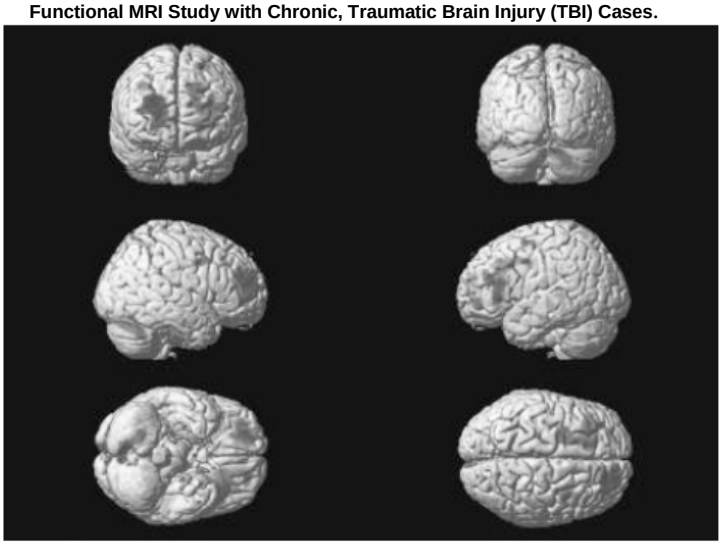

FIG. 3. Areas where patients showed significantly lower activation than did controls for the 2-back > 0-back comparison after covariation for performance. Significant differences are observed in right superior and left middle frontal regions ($p = 0.005$). Statistical Parametric Maps with left as left, according to neurological convention.

Digits Backwards and Letter-Number Sequencing subtests from the WAIS-III.

Sanchez-Carrion et al., *J. of Neurotrauma*, 2008

Naeser & Saltmarche, NAALT, 2009

Case Report: Transcranial LED to Treat Cognitive Dysfunction in Chronic, mild TBI

Summary of Accident:

59 Yr. F, *closed-head injury*, motor vehicle accident (MVA) in April, 1997.

She was the driver (small, compact car) hit from behind, while stopped at a red light. Hit by a large, heavy car driven at a high rate of speed. Her head snapped back, and *hit a very rigid, head-rest*. She was wearing the seat-belt, and did not lose consciousness.

She called the Police; but drove herself home.

Later that evening, the increasing headache caused her to seek medical attention in an ER, at her local hospital.

Head X-Rays and Brain MRI scan were normal.
(Brain MRI scans continued to be considered normal, even years later.)

Returned home with pain meds for the headache and sub-occipital neck pain.

Naeser & Saltmarche, NAALT, 2009

Case Report: Transcranial LED to Treat Cognitive Dysfunction in Chronic, mild TBI

Summary of initial 2 Months, post-Accident

She was told to stay home and *rest for 2 months*. She also slept a great deal.

She *tried to return to work after 2 months*, but could not function, due to confusion, inability to remember what people said to her, and inability to focus on her computer work.

She had 2 Master's Degrees; had written 3 books; knew 3 languages; in Mensa.
She had been Director of Marketing and a Sales Development Specialist for an Internet Marketing Company.
She had also *taught web-design on the graduate level, at a university*.

She had to *resign from all work*, due to "cognitive dysfunction."

She was diagnosed by a Neurologist as having "Post-Concussive Syndrome," and was told she might never recover, even for 5 years.

Naeser & Saltmarche, NAALT, 2009

Case Report: Transcranial LED to Treat Cognitive Dysfunction in Chronic, mild TBI

Summary of Cognitive Behavioral Evaluation and Treatment Programs

At 2 years post-MVA, her *cognitive abilities were evaluated* for 40 hours at a rehabilitation institute.

Her Divergent Reasoning abilities were significantly impaired across all verbal tasks.

Her *Executive Function ability was severely impaired*, where a task required that she plan moves ahead in her mind (such as in a game of chess).

She had a *vulnerability to emotional distress, and depression*, (not uncommon with this disorder)

Naeser & Saltmarche, NAALT, 2009

Case Report: Transcranial LED to Treat Cognitive Dysfunction in Chronic, mild TBI

Summary of Cognitive Behavioral Treatment Programs, 2 - 4 Yr. post-MVA

At 2 Yr. post-MVA, she underwent two, 20-week "*Remedial Training for Cognitive Function"* programs with peers of similar education and background, who had similar cognitive deficits due to TBI or myocardial infarction with hypoxia to brain.

However, few of her old skills returned, no new skills were acquired, and her original disabilities remained.

After completion of the second, 20-session program, she was still unable to perform any work. There was a suicide attempt with drug overdose.

At 4 Yr. post-MVA, she received further "Behavioral Therapy Sessions," at a rehabilitation institute in a different state.
39 one-hour (one-on-one) "Cognitive Training Sessions," followed by 39 one-hour "Personal TBI Acceptance Sessions"

She could work on her computer for 20 minutes.

Naeser & Saltmarche, NAALT, 2009

Case Report: Transcranial LED to Treat Cognitive Dysfunction in Chronic, mild TBI

Beginning of LED Treatments, at 7 Yr. post-MVA

At 5 Yr. post-MVA, she and her husband moved to another state.

At 7 Yr. post-MVA, she answered an Ad for "*Free LED treatments for Pain.*"

Following the MVA, she had developed painful, knee arthritis.

She received two, LED treatments on both knees, one week apart. Resulted in "*…a reduction of swelling by 66% and a reduction in pain by 80%*."
[FDA-cleared indication of MedX Device use]

She then requested that the doctor *place the LED cluster heads on her head, "to treat her brain."*

After consultation with A. Saltmarche, RN, MHSc, in Toronto, and appropriate "Informed Consent" was obtained, the transcranial, LED treatments were initiated. [Off-label MedX Device use]

Naeser & Saltmarche, NAALT, 2009

1st Transcranial, LED Treatment (May, 2004)
7 years post-MVA (in Dr.'s Office)

High Intensity, LED Cluster Head Device, used at Office:
MBM1100 Console, with 3 Square-shaped LED Cluster Heads

Each *Square-shaped Cluster-head* dimension: 4.4 cm x 4.4 cm
(approximately 1.75 inch x 1.75 inch)
Treatment Area: 19.39 cm^2
Each cluster head contained ***49 diodes***:
40 *near-infrared* ***870 nm*** *diodes*, 12.25 mW each
9 *red* ***633 nm*** *red diodes*, 1 mW each
Total Power: 500 mW (±20%) Continuous Wave, CW
Power density: 25.8 mW/cm^2 (±20%)
1 J = 2 sec
1 J/cm^2 = 38.8 sec

Naeser & Saltmarche, NAALT, 2009

1st Transcranial, LED Treatment (May, 2004)
7 years post-MVA (in Dr.'s Office)

Office Notes:

Treatment Loci: Left and Right Forehead areas
8 J/cm^2 to each area
Treatment Time: 5 minutes, 10 seconds per area

Patient Reaction:
Drove herself home (30 minutes)
Slept through dinner, could not get up.
Slept most of the next day.
Day 3, post- 1st LED Tx: Improved concentration and focus.
Able to ***work at her computer, 40 minutes***
Previously (for 7 Yr. post-MVA), able to work at her computer for **only 20 minutes**.

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High Intensity, LED Treatment Considerations

Only *2 to 3% of energy penetration from skin* on the scalp surface, is estimated to *reach brain cortex* 1 cm deep, from the scalp or skin surface.

Only 0.2 to 0.3% energy penetration from scalp on skin surface, is estimated to reach 2 cm deep (into the white matter).
(M. Hamblin, Ph.D., Wellman Center for Photomedicine, MGH, personal communication; Wan, Parrish, Anderson et al., 1981)

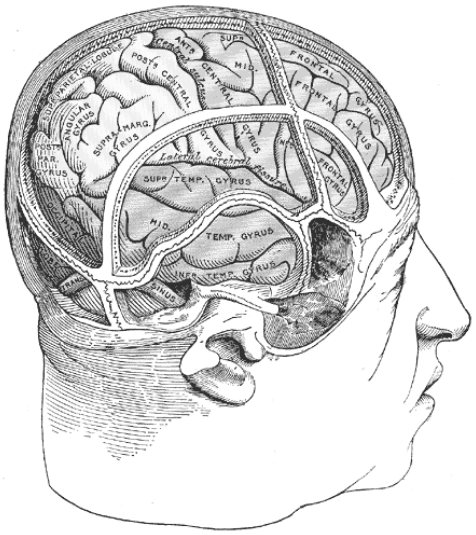
Thus, *3% of 8 J/cm^2* delivered to skin on L and R temple areas, would deliver *only 0.24 J/cm^2 to brain cortex*.
This is a very low dose.

If there is an effect, it is unclear whether the effect may be related to:
a. The photons *reaching the grey and white matter of the brain?*
OR
b. The photons may be *stimulating shallow acupuncture points* located on the surface of the scalp or skin?
OR
c. Possible "Systemic Effects" (Mary Dyson, Ph.D., personal communication)

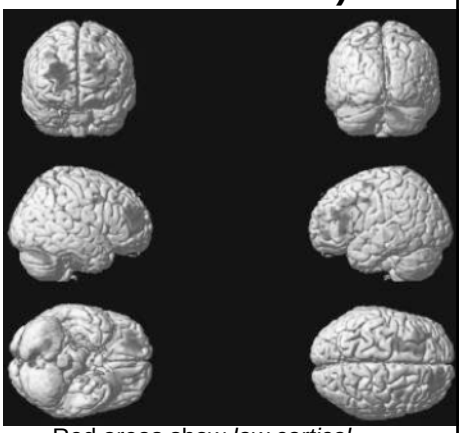
Naeser & Saltmarche, NAALT, 2009

1st LED Treatment: L & R Forehead areas

8 J/cm^2 per area (0.24 J/cm^2 to cortex)



Location of Gyral Areas of Brain Cortex, in Relationship to Bone Suture Lines of Skull.
(Gray1197.png)



Red areas show *low cortical activation* on functional MRI in chronic, TBI cases (post-MVA) with "cognitive dysfunction."
Sanchez-Carrion et al., 2008

Naeser & Saltmarche, NAALT, 2009

2nd Transcranial LED Treatment (1 Week Later)

7 years post-MVA (in Dr.'s Office)

Office Notes:

Treatment Loci: Left and Right Forehead areas

8 J/cm^2, each area (0.24 J/cm^2)

Treatment Time: 5 min, 10 sec per area

Patient Reaction:

Her husband drove her to the appointment.
She had no return of excess sleepiness.
Continued to have improved concentration and focus.
Able to *work at her computer, **40 minutes***

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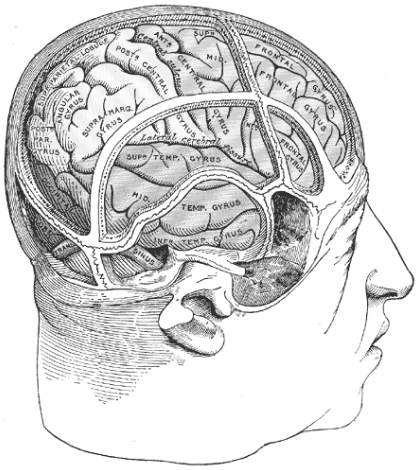
3rd LED Treatment: L & R Forehead; midline at hairline; and L & R Temples, 8 J/cm^2 per area (0.24 J/cm^2 to cortex)



Location of Gyral Areas of Brain Cortex, in Relationship to Bone Suture Lines of Skull.
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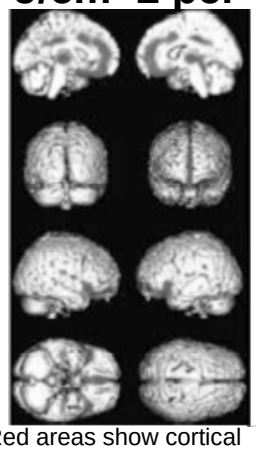


Red areas show cortical locations of *low glucose metabolism on PET scans, in* chronic, TBI cases (post-MVA) with cognitive dysfunction.
Kato et al., 2007

Naeser & Saltmarche, NAALT, 2009

Weeks 3 - 8 of Treatments (1x / Week) at Dr.'s Office

Office Notes:

Treatment Loci: Left and Right Forehead areas above eyebrows; plus a midline forehead area, at the front hairline; Left and Right Temple areas.
Total = 5 areas
Gradually increased from 8 J/cm^2 per area, up to 20 J/cm^2 per area

Treatment Time: Gradually increased from 5 min, 10 sec to up to 12 min, 54 sec, per area.

Patient Reaction:

She had no return of excess sleepiness.
Continued to have improved concentration and focus.
After 8 Weeks, able to work at her computer, 3 hours

Naeser & Saltmarche, NAALT, 2009

For 5 more Months, the patient continued with 1x / Week, Transcranial LED Treatments in the Dr.'s Office (7 Months)

Patient Overall Reaction:
Able to drive herself to and from appointments.

Her time on the *computer was focused for **3 hours at a time***.

Her *mood became more stabilized*,
and *outbursts of anger, greatly reduced*.

She had received a total of approximately 28 transcranial, LED treatments.

Naeser & Saltmarche, NAALT, 2009

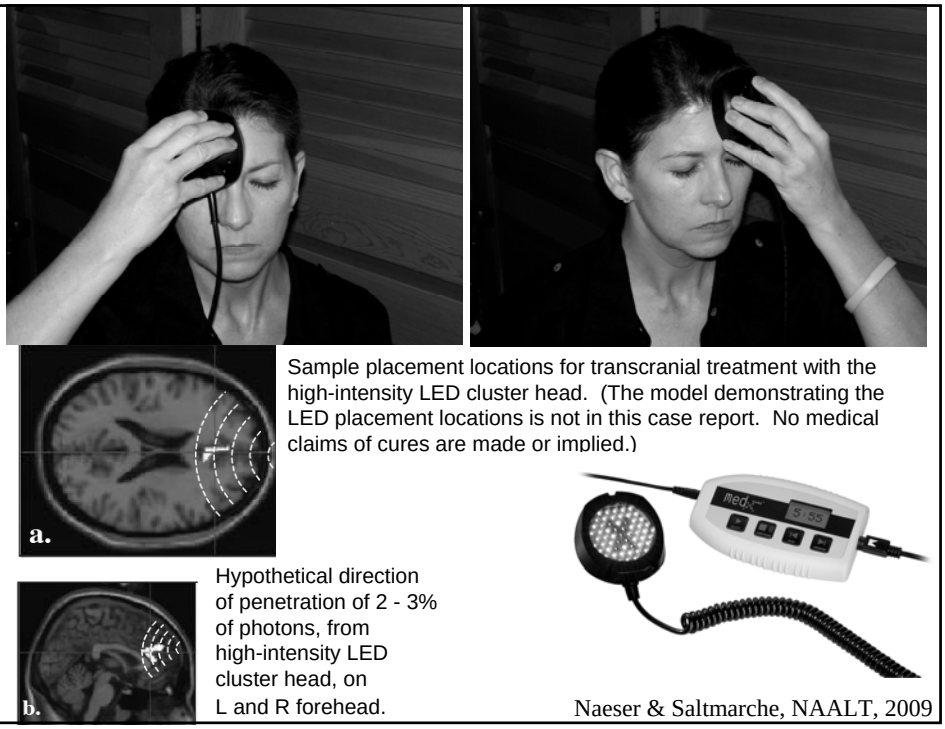
After 7 Months of LED Tx.'s, 1x / Wk. at Dr.'s Office, in January, 2005, she *obtained Home Treatment Unit*

[Off-label MedX Device use]

with a single LED Cluster Head (7 Yr., 9 Mo. post-MVA)

Circular-shaped, Cluster-head diameter: 53.45 mm (2.1 inches)
Treatment Area: 22.48 cm^2
Single cluster head contained ***61 diodes***:
52** near-infrared **870 nm diodes
9** red **633 nm diodes
Each diode was 12–15 mW
Total optical output power: 500 mW (±20%) CW
Power density: 22.2 mW/cm^2 (±20%)
1 J = 2 sec
1 J/cm^2 = 45 sec

She treated 6 spots per night,10 min per area; 13.3 J/cm^2 per area (0.4 J/cm^2 to brain cortex). Naeser & Saltmarche, NAALT, 2009


a.
b.
Sample placement locations for transcranial treatment with the high-intensity LED cluster head. (The model demonstrating the LED placement locations is not in this case report. No medical claims of cures are made or implied.)
Hypothetical direction of penetration of 2 - 3% of photons, from high-intensity LED cluster head, on L and R forehead.
Naeser & Saltmarche, NAALT, 2009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The MedX Console Unit has three LED Cluster Heads.

Three LED cluster heads **may be used in three different locations,** ***at the same time*****.**

The usual treatment time is 10 minutes per location.

Here, two LED cluster heads are held in place on the head, with *a loose-fitting elastic cap*.

The LED cluster head placed on the sole of the foot (acupuncture point, Kidney 1), is held in place with a soft, flexible, *elastic band, secured with a velcro strap*.

Naeser & Saltmarche, NAALT, 2009

Notes from Patient, following Home Treatments:

Treatment Loci:

Left & Right Forehead areas; Left and Right Temple areas

Midline at front hairline (Combined with foot points, see below.)

Left and Right areas posterior-superior to the ears (Angular gyrus area), ⟶ "Able to remember what she read."

Left and Right base of skull, ⟶ "Removed sensitivity of L scalp area when hair was being cut there (had been present for previous 7 years); improvement in reflexes on left side of body."

Center, top of her head, ⟶ "Able to work better with numbers, and math."

Treatment Time:

10 minutes per area, CW; **13.3 J/cm^2 per area**
(0.4 J/cm^2 to brain cortex)

Prefers to treat at bedtime, as her sleep improves.

She treats 6 scalp areas per night (locations vary). (Also acupuncture points, on sole of foot - Kidney 1; or top, base of toes - Ba Feng.)

Naeser & Saltmarche, NAALT, 2009

Patient's Overall Reaction:

Able to drive.
Able to perform computer work for 3 hours at a time.
"Decision-making and verbal memory, incredibly better."
"Improved self-awareness of both limitations and successes."
Also continues to treat pain in her knees (arthritis), if pain is present in the mornings.

Remaining Cognitive Problems:

She *still cannot multi-task well*, her chief complaint now, after 4 years of home treatments with the LED cluster head.

She still needs to make notes, to be sure all things are accomplished, but her *overall quality of life is much improved*.

Naeser & Saltmarche, NAALT, 2009

***She needs to treat almost daily*.**

If she stops the transcranial LED treatment for 2 to 7 weeks, ***she slowly regresses***.
Her focus and attention become compromised.
She cannot work for hours on her computer and her balance becomes poor.
As is common with TBI, she has fallen sometimes, since the MVA. This includes 2x, since acquiring LED home treatment unit.
Using the *LED cluster head, transcranially, as soon as possible after the fall,* helps her to *recover faster*.
When re-starting transcranial LED treatments, she starts with a ***shorter treatment time*** and lower J/cm^2.
Initial Treatment Time, Round Cluster: 6 min per area; **8 J/cm^2**; 0.24 J/cm^2 to brain cortex
Preferred Treatment Time (at night): 10 min per area; **13.3 J/cm^2** (estimated 0.4 J/cm^2 to brain cortex).

Naeser & Saltmarche, NAALT, 2009

High Intensity, LED Treatment Considerations

Only *2 to 3% of energy penetration from skin* on the scalp surface, is estimated to *reach brain cortex* 1 cm deep, from the scalp or skin surface.

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(M. Hamblin, Ph.D., Wellman Center for Photomedicine, MGH, personal communication; Wan, Parrish, Anderson et al., 1981)

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OR

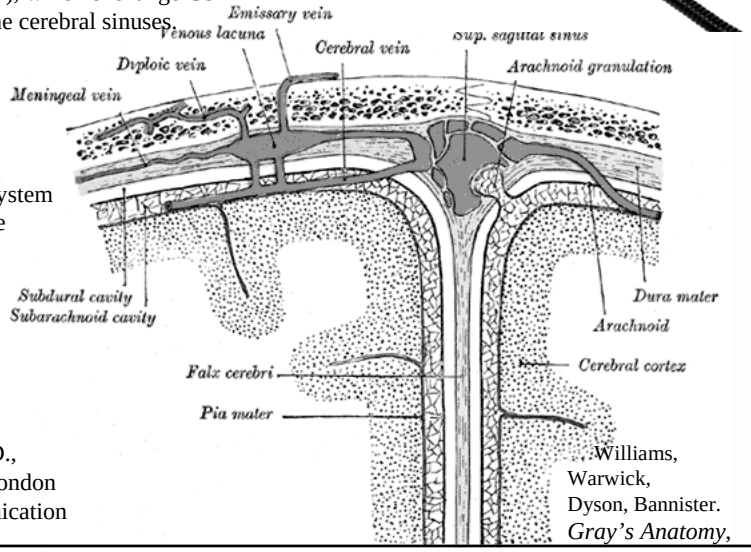
c. Possible "Systemic Effects" (Mary Dyson, Ph.D., personal communication)

Naeser & Saltmarche, NAALT, 2009

The red, and near infra-red photons may penetrate best through suture lines in the skull, and through emissary veins located throughout the skull.

The emissary veins communicate with the Arachnoid Granulations (Villi), which exchange CSF into the veins in the cerebral sinuses.

Thus, the photons may enter the emissary veins and CSF, and the venous drainage system (which leads to the jugular vein). This system may also be a factor in Transcranial, Laser or LED therapy.



Mary Dyson, Ph.D., King's College, London Personal Communication

Williams, Warwick, Dyson, Bannister. *Gray's Anatomy,*

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Neuroscience Letters 327 (2002) 53–56

Neuroscience Letters

www.elsevier.com/locate/neulet

Functional magnetic resonance imaging detects activation of the visual association cortex during laser acupuncture of the foot in humans

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Abstract

The aim of this study was to investigate the effect of laser acupuncture on cerebral activation. Using functional magnetic imaging (fMRI) cortical activations during laser acupuncture at the left foot (Bladder 67) and dummy acupuncture, were compared employing a block design in ten healthy male volunteers. All experiments were done on a 1.5 Tesla magnetic resonance scanner equipped with a circular polarized head coil. During laser acupuncture, we found activation in the cuneus corresponding to Brodmann Area (BA) 18 and the medial occipital gyrus (BA 19) of the ipsilateral visual cortex. Placebo stimulation did not show any activation. We could demonstrate that laser acupuncture of a specific acupoint, empirically related to ophthalmic disorders, leads to activation of visual brain areas, whereas placebo acupuncture does not. These results indicate that fMRI has the potential to elucidate effects of acupuncture on brain activity.

Keywords: Laser acupuncture; Acupoint Bladder 67; Functional magnetic resonance imaging; Visual cortex

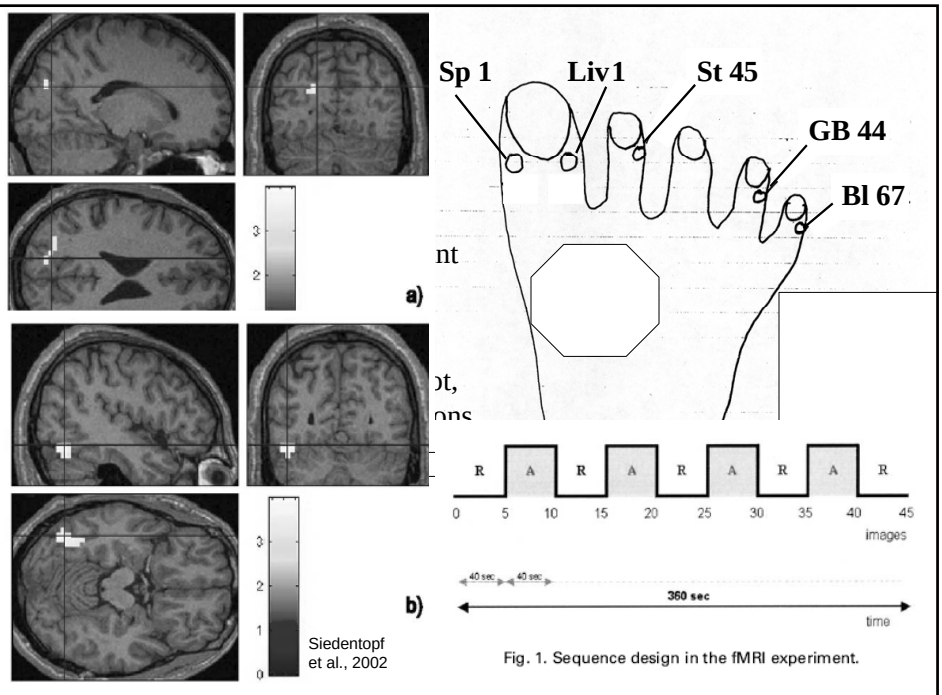

Fig. 1. Sequence design in the fMRI experiment.

Fig. 2. Ipsilateral, occipital cerebral activation pattern induced by laser acupuncture to Bl 67. Naeser & Saltmarche, NAALT, 2009

Considerations for Future Transcranial, High-intensity LED Treatments

With current LED treatment protocol, the energy density and the power density *may be too low*.

Treatment for only 10 minutes per area (13.3 J/cm^2) at scalp surface, is likely *only delivering 0.4 J/cm^2 to local brain cortex* (estimate is 3% of NIR photons will reach local brain cortex).

(Wan, Parrish, Anderson, Madden, 1981).

Therefore, it is estimated that MedX LED clusters would deliver approximately *1 J/cm^2 in 25 minutes*, or *4 J/cm^2 in 100 minutes*.

The patient states that she is “comfortable with the LED in place for 10 minutes, but is not comfortable with longer than that."

Naeser & Saltmarche, NAALT, 2009

DARPA Soldier Self Care: Rapid Healing of Laser Eye Injuries with Light Emitting Diode Technology

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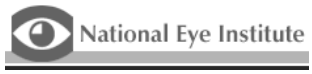


Lead researcher at the University of Sunderland Dr Abdel Ennaceur and Durham University's Dr Paul Chazot are pictured with Dr Gordon Dougal and a prototype cognitive helmet. (Credit: Image courtesy of University of Sunderland)

http://www.rexresearch.com/dougal/dougal.htm/

Suggestions, Future High-intensity LED Treatments:

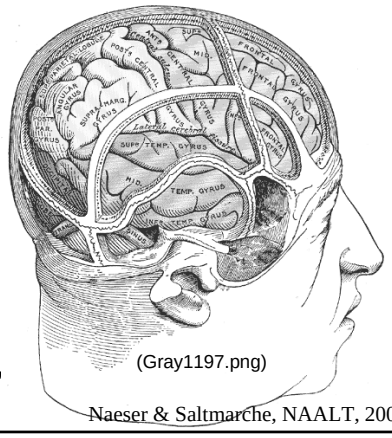
Stronger LED clusters with *higher power density*, could reduce the necessary overall treatment time, per area.

Optimal J/cm^2 (and mW/cm^2) still to be determined, as well as number of treatments, and duration of treatment periods.

Possible need for *long-term*, *home-treatment programs*.

Treatment for other CNS disorders where "cognitive dysfunction" is present include Stroke, Dementia (vascular or Alzheimer's), *Sports-related traumatic brain injury*, Football and Soccer players, etc.

Further research with randomized, controlled trials is necessary.



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Naeser & Saltmarche, NAALT, 2009

REVIEW, Eight Cellular Effects of LLLT/LED relevant to TBI:

Michael Hamblin, PhD, Wellman Center for Photomedicine, Massachusetts General Hospital

1. Induction of *reactive oxygen species* and *NF-kB activation*

The present hypothesis is ***that LLLT produces low levels of reactive oxygen species*** (ROS) in mitochondria of illuminated cells, and that these ROS cause NF-kB activation via the redox sensitive sensor enzyme protein kinase D1 (Storz, 2007).

Induction of low levels of ROS by LLLT may actually prevent major ROS-mediated damage occurring in the brain after TBI.

The mitochondrial superoxide dismutase (MnSOD) is one of the most upregulated genes after NF-kB activation (Sompol et al., 2006).

Another ***highly upregulated gene after NF-kB activation*** and ***after LLLT*** is ***heat-shock protein 70*** (Zhang et al., 1994).

This is a molecular chaperone for protein molecules and ***prevents mis-folding*** and unwanted protein aggregation.

Heat stress preconditioning (Shein et al., 2007) and various mild stresses (Guo et al., 2001) have been shown to ***prevent neuronal death after TBI***.

2. *Increased ATP formation* and *improved mitochondrial function* in injured brain will allow ATPase pumps to pump out Na+/Ca++ ions and *prevent neuronal death*

Impaired cerebral energy metabolism may be a ***major contributor to the secondary injury cascade*** that occurs after TBI.

Significant reductions in mitochondrial function have been found ***after TBI*** in both animals (Verweij et al., 1997) and humans (Verweij et al., 2000).

Many reports studying ***effects of LLLT on isolated mitochondria*** and on multiple cell lines ***including neurons*** (Oron et al., 2007), have shown ***increased ATP production,*** and ***increased mitochondrial respiration*** and function (Karu et al., 1995; Passarella et al., 1984; Pastore et al., 1996).

Michael Hamblin, PhD

3. The *anti-apoptotic effects*, and increase in mitochondrial potential due to LLLT, *will reduce neuronal and glial cell death*

Traumatic axonal injury causes ***neuronal and glial cell death***, and apoptotic and necrotic neurons have been identified within contusions in the acute post-traumatic period, ***and in regions remote from the site of impact in the days and weeks after trauma***.

Many studies demonstrate the ***anti-apoptotic effect of LLLT*** especially ***on neurons subjected to various toxic insults*** such as

cyanide (Liang et al., 2006)

tetrodotoxin (Wong-Riley et al., 2005)

methanol (Eells et al., 2003)

Michael Hamblin, PhD

4. The *anti-inflammatory effects of LLLT* will reduce key inflammatory mediators (TNFα, PGE2) in the injured brain

Animal studies described ***up-regulation of COX-2, PGE and PGD expression*** in two rat models of TBI (Kunz et al., 2002).

Reports (Castano et al., 2007) demonstrate that ***LLLT reduces COX-2*** expression levels and ***reduces prostaglandins*** in multiple animal models as well as in vitro (Aimbire et al., 2005; Albertini et al., 2007; Sakurai et al., 2000).

Another key inflammatory mediator that has been implicated in pathogenesis of TBI is the cytokine tumor necrosis factor alpha (TNFα).

There are multiple reports showing that ***LLLT reduces TNFα levels in arthritis*** (Aimbire et al., 2006) and other animal models of inflammation.

Michael Hamblin, PhD

5. LLLT is expected to *reduce brain edema* and hence *ameliorate neuronal damage*

Brain edema resulting from TBI or ischemia exhausts volume reserve and leads to raised intracranial pressure and brain herniation.

Studies of LLLT in both various animal models (Albertini et al., 2004) and in rat arthritis (Castano et al., 2007) and in numerous clinical applications (Carati et al., 2003; Markovic et al., 2007) have demonstrated that ***LLLT is particularly effective in reducing edema***.

Michael Hamblin, PhD

6. LLLT has been shown to *increase antioxidant capacity* in *ischemic tissues*

Many reports show that ***reactive oxygen species*** or ***oxidative stress*** is involved in the ***pathogenesis of brain damage after TBI***.

LLLT treatment of ischemic gastrocnemius muscle in rats gave a significant ***increase in global antioxidant measure*** and an ***increase in heat shock protein 70*** (Avni et al., 2005).

Michael Hamblin, PhD

7. LLLT has been shown to be effective in *stimulating repair of neurons* (both peripheral and in spinal cord) and *could increase neurogenesis in TBI*.

In recent years it has become realized that
neurogenesis in damaged brain after TBI
is ***not the rare event*** it was once thought to be
(Richardson et al., 2007).

Byrnes and colleagues (Byrnes et al., 2005) showed that
adult rats that underwent a T9 dorsal hemisection,
followed by treatment with an 810-nm, 150 mW diode laser showed
significant improvement in axonal regeneration
and functional recovery.

Michael Hamblin, PhD

8. LLLT increases expression (and activation) of growth factors such as *TGF-β and VEGF* that *may contribute to positive brain remodeling after TBI*

There has been a report (Leung et al., 2002) that
in a rat stroke model,
transcranial LLLT triggered
the ***expression of TGF-β1*** (as well as reducing NO levels).

Tuby et al. (2006) showed that
in a rat heart infarcts model,
LLLT significantly increased
VEGF expression levels and
this correlated with ***increased angiogenesis***.

Michael Hamblin, PhD

Part 3. Studies with LLLT, Laser Acupuncture

to treat Paralysis in Stroke

and

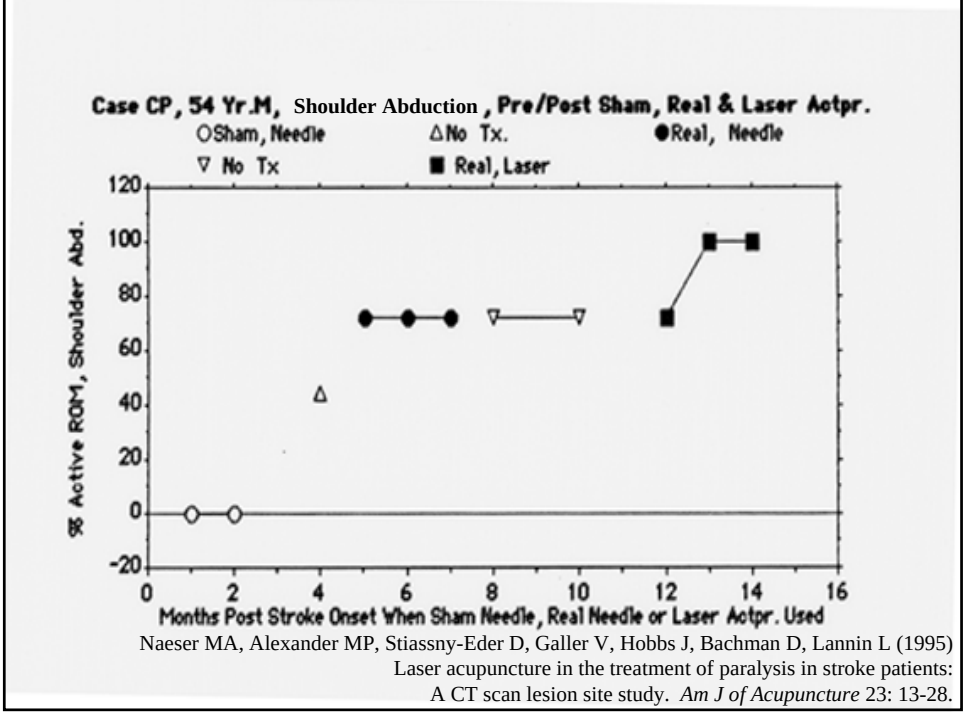
Pain in Carpal Tunnel Syndrome.

Hua Shan Hospital
Shanghai, China, 1985.

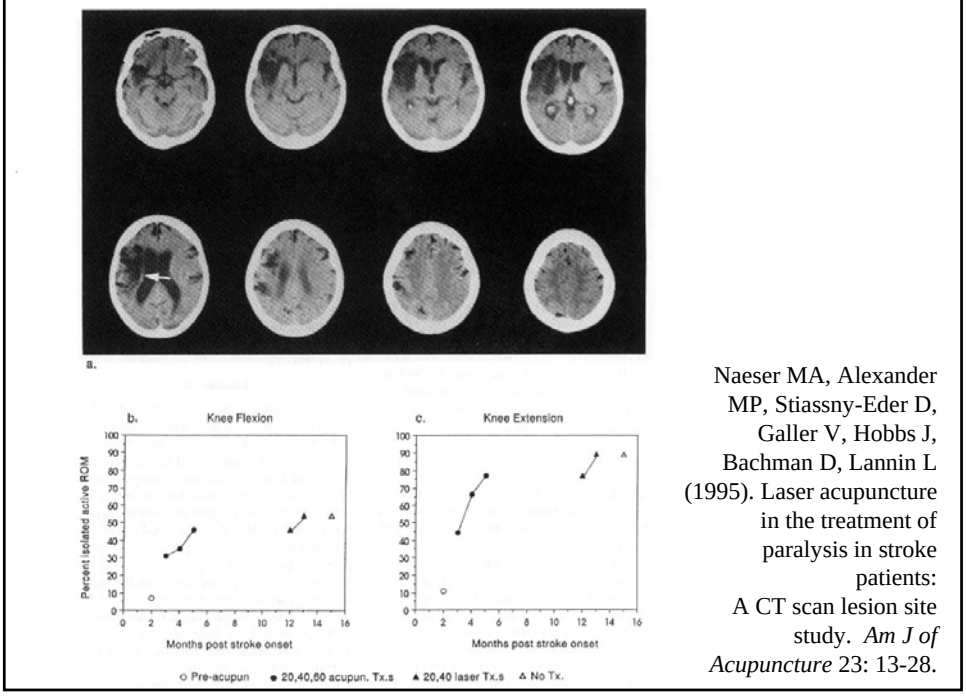
Neurological and
Dermatological
Research Institute

Laser Acupuncture to Treat
Paralysis in Stroke

Red-beam laser used on acupuncture points to treat paralysis due to stroke.



Naeser MA, Alexander MP, Stiassny-Eder D, Galler V, Hobbs J, Bachman D, Lannin L (1995) Laser acupuncture in the treatment of paralysis in stroke patients: A CT scan lesion site study. *Am J of Acupuncture* 23: 13-28.



Naeser MA, Alexander MP, Stiassny-Eder D, Galler V, Hobbs J, Bachman D, Lannin L (1995). Laser acupuncture in the treatment of paralysis in stroke patients: A CT scan lesion site study. *Am J of Acupuncture* 23: 13-28.

Case FJ, 48 Yr. F., 4 Yr. Post Stroke. Left Hemiplegia

Laser Acptr. Tx.'s

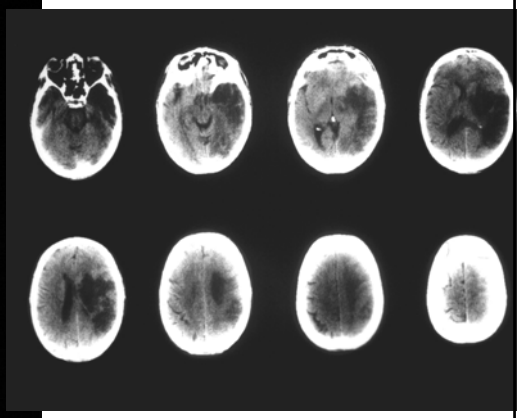
Arm/Leg, Poor Response

However, Post Laser Tx.'s, loosened Achilles Tendon, improved walking ability

Face, Good Response

Left side of face "lifted" to become more symmetric with the right.

Post 5 laser tx.'s, ability to control food and liquids in left side of mouth. Preceding 4 Yrs., unable to do so.



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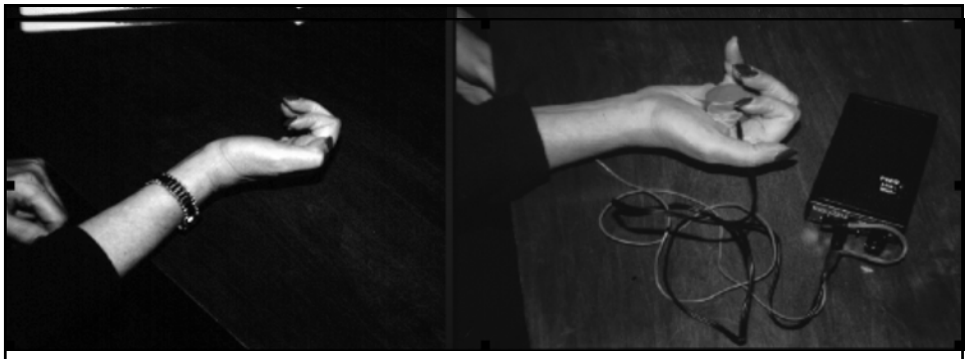


BEFORE TREATMENT: Right Hand *spasticity still present,* 1.5 Yr. Poststroke

Microamps TENS device (MicroStim 100) will be used for 20 Minutes,

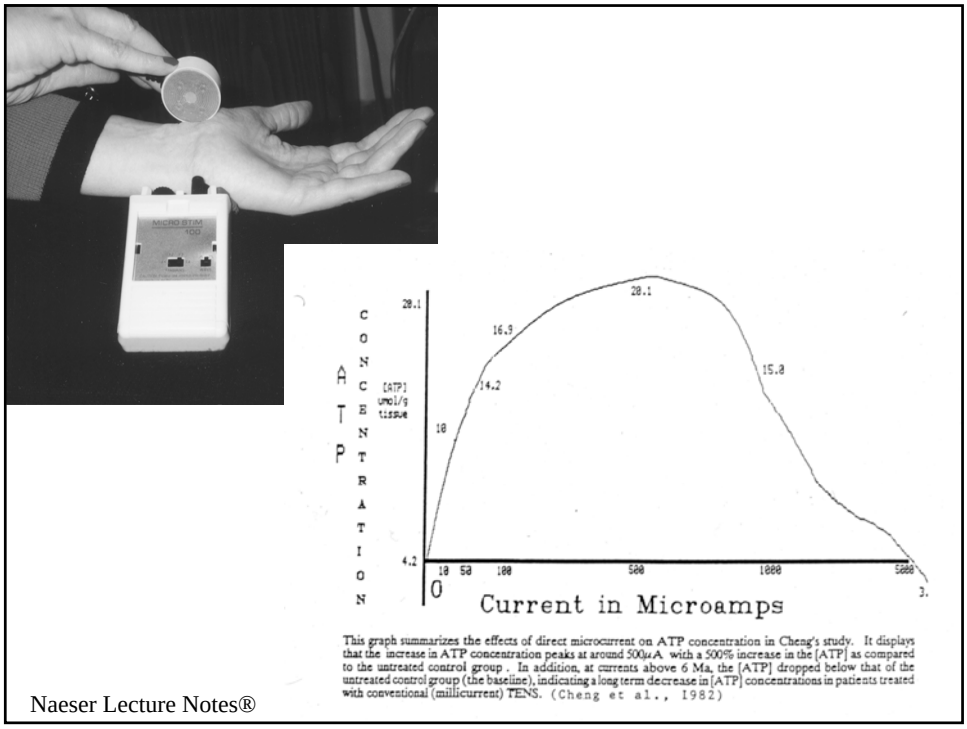
on two Acupuncture Points: HRT 8 and TW 5

High Frequency, 292 Hz., 2 min. *(subthreshold)*

Low Frequency, 0.3 Hz., 18 min. *(subthreshold)*

PLUS, Red-Beam Laser Acupuncture on the finger tips, 4 J/cm^2 per point

Naeser Lecture Notes®



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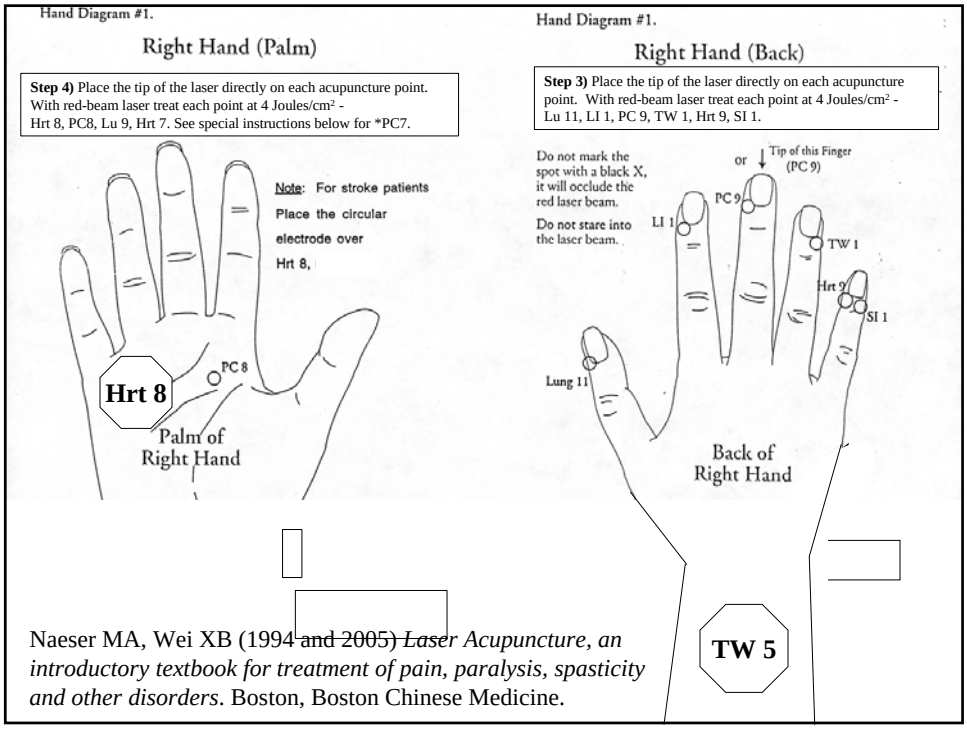


Naeser MA, Wei XB (1994 ~~and 2005)~~ *Laser Acupuncture, an introductory textbook for treatment of pain, paralysis, spasticity and other disorders*. Boston, Boston Chinese Medicine.

BEFORE TREATMENT:

Hand spasticity still present
1.5 Yr. Poststroke

1st Treatment
Naeser Laser Hand Treatment

Microamps TENS (Hrt 8, TW 5)
and
Red-beam Laser (Jing-Well Pts.)

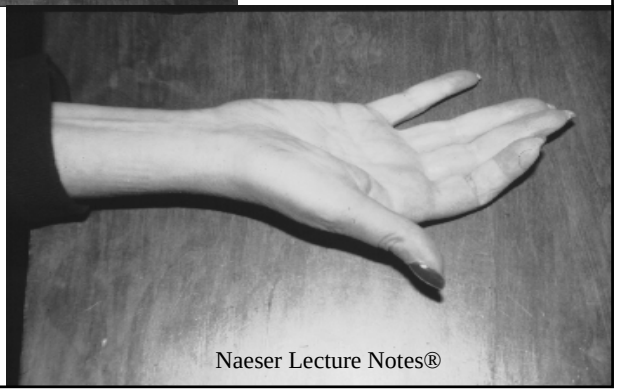
AFTER TREATMENT:

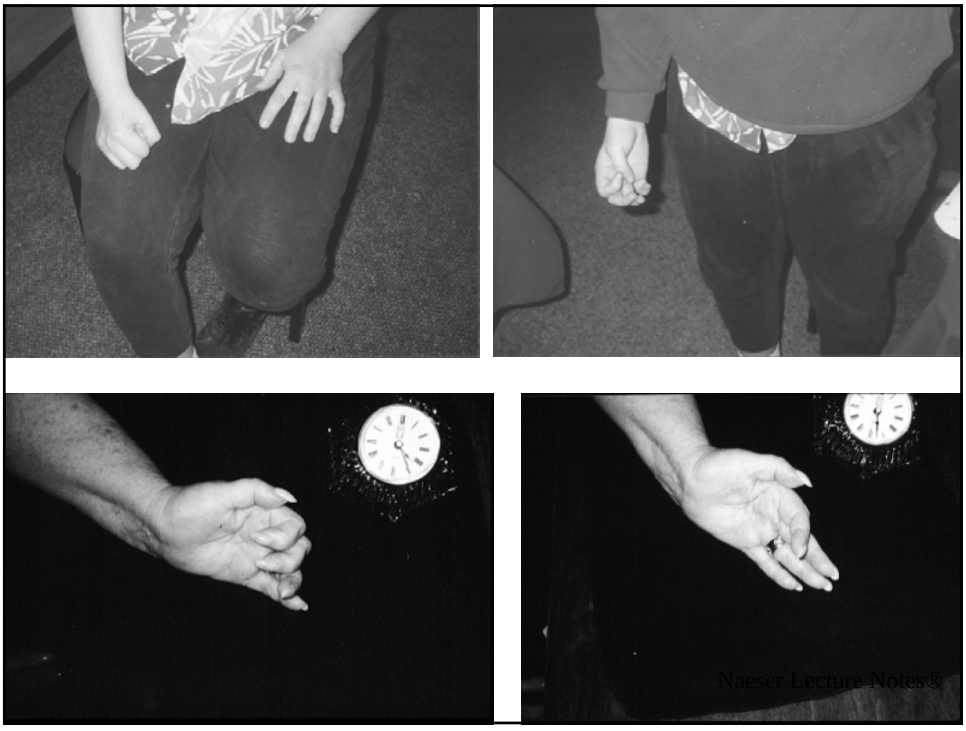
Post- 1st, 20-Minute Treatment

Hand opens
Fingers have more extension
and less spasticity

Requires more treatments,
to retain more lasting effect.

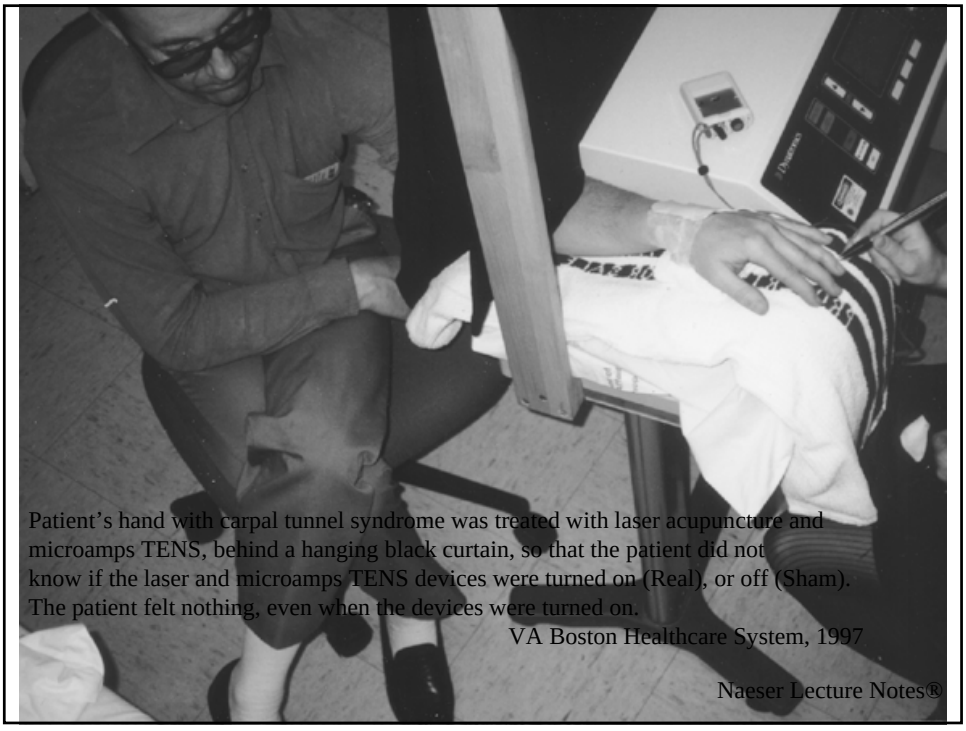
Patient can treat him/herself.





Carpal Tunnel Syndrome - *Laser Acupuncture*

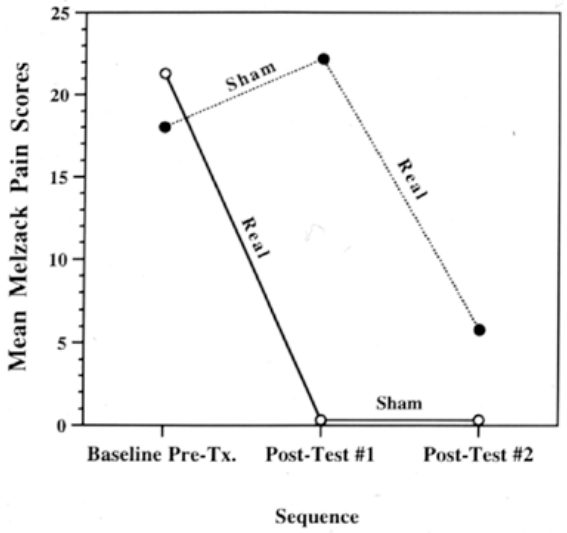
Authors	Number Cases Real Laser and Microamps TENS 11 Chronic	Number Cases Sham Laser and Microamps TENS 11 Chronic
Naeser, Hahn, Lieberman, Branco, 2002, Arch PM & R	Duration of Pain: 3 Mo.'s - 2 Yr.'s	Duration of Pain: 3 Mo.'s - 2 Yr.'s
Boston Univ. School of Medicine	Red-beam Laser 15 mW, HeNe, CW 1 - 7 Joules per Aceptr. Point plus Microamps TENS	Sham Laser and Sham Microamps TENS
Boston V.A. Medical Center	12 Treatments	12 Treatments



Patient's hand with carpal tunnel syndrome was treated with laser acupuncture and microamps TENS, behind a hanging black curtain, so that the patient did not know if the laser and microamps TENS devices were turned on (Real), or off (Sham). The patient felt nothing, even when the devices were turned on.

VA Boston Healthcare System, 1997

Naeser Lecture Notes®



Naeser MA, Hahn K-A K, Lieberman BE, Branco KF (2002) Carpal Tunnel Syndrome Pain Treated with Low-Level Laser and Microamps TENS. *Archives of Physical Medicine and Rehabilitation* 83: 978-988.

Table 2. Melzack Pain Scores

		Real Treatments				Sham Treatments			
	Cases	Pre	Post	Δ Post minus Pre (%)		Pre	Post	Δ Post minus Pre (%)	
		Entry Baseline	Post-Test #1				Post-Test #2		
Real 1st	1 - Mild CTS	15	0	-15	(-100%)	0	0	0	(0%)
	2 - Mild CTS	23	0	-23	(-100%)	0	0	0	(0%)
	3 - Mild CTS	23 *	9 *	-14 *	(-60.8%)	9 *	0 *	-9 *	(-100%)
	4 - Mod. CTS	26	1	-25	(-96.2%)	1	1	0	(0%)
	Mean (n=3)	21.3	0.33	-21	(-98.7%)	0.33	0.33	0	(0%)
	S.D.	5.69	0.58	5.3	(2.3)	0.58	0.58	0	(0%)
			Post-Test #2			Entry Baseline	Post-Test #1		
Real 2nd	5 - Borderline/Mild CTS	26	0	-26	(-100%)	24	26	+2	(+8.3%)
	6 - Mild CTS	36	2	-34	(-94%)	14	36	+22	(+157%)
	7 - Mild CTS	1 *	1 *	0 *	(0%)	14 *	1 *	-13 *	(-92.8%)
	8- Mod. CTS	24	18	-6	(-25%)	29	24	-5	(-17.2%)
	9 - Mod. CTS	5	0	-5	(-100%)	8	5	-3	(-37.5%)
	10 - Mod. CTS	20	9	-11	(-55%)	15	20	+5	(+33.3%)
	11 - Mod. CTS	2 *	2 *	0 *	(0%)	33 *	2 *	-31 *	(-93.9%)
	Mean (n=5)	22.20	5.80	-16.40	(-74.8%)	18.00	22.20	+4.20	(+28.78%)
	S.D.	11.28	7.76	12.93	(33.58)	8.40	11.28	10.71	(76.46)
	Pooled Groups								
	Mean (n=8)	21.87	3.75	-18.13	(-88.78%)	11.38	14.00	2.62	(17.99%)
	S.D.	9.06	6.52	10.45	(28.27)	11.14	14.17	8.38	(59.69%)
				t = 4.66				t = -0.89	
	Probability			p = .0035				p = .41	

* Case was a placebo responder during First or Second Sham Treatment Series; data excluded from t-test comparisons.

Naeser MA, Hahn K-A K, Lieberman BE, Branco KF (2002) Carpal Tunnel Syndrome Pain Treated with Low-Level Laser and Microamps TENS. *Archives of Physical Medicine and Rehabilitation* 83: 978-988.

Table 3. Median Nerve, Sensory Peak Latencies

	Cases	Real Treatments Pre msec.	Real Treatments Post msec.	Real Treatments Δ Post minus Pre msec.		Sham Treatments Pre msec.	Sham Treatments Post msec.	Sham Treatments Δ Post minus Pre msec.
		Entry Baseline	Post-Test #1				Post-Test #2	
Real 1st	1 - Mild CTS	4.32	4.00	-0.32	Sham 2nd	4.00	3.92	-0.08
	2 - Mild CTS	3.76	3.60	-0.16		3.60	3.60	0.00
	3 - Mild CTS	Absent *	5.00 *	- *		5.00	4.40	-0.60
	4 - Mod. CTS	3.6	3.60	0.00		3.60	3.80	+0.20
	Mean (n=3)	3.89	3.73	-0.16	(n=4)	4.05	3.93	-0.12
	S.D.	0.38	0.23	0.16		0.66	0.34	0.34
		Post-Test #2				Entry Baseline	Post-Test #1	
	5 - Borderline/Mild CTS	3.20	2.80	-0.40		3.20	3.20	0.00 *
	6 - Mild CTS	3.92	3.84	-0.08		4.40	3.92	-0.48
Real 2nd	7 - Mild CTS	4.16	4.08	-0.08	Sham 1st	4.16	4.16	0.00
	8 - Mod. CTS	3.20	3.00	-0.20		No Data *	3.20 *	- *
	9 - Mod. CTS	5.36 *	Absent *	- *		Absent *	5.36 *	- *
	10 - Mod. CTS	Absent *	Absent *	- *		Absent *	Absent *	- *
	11 - Mod. CTS	5.28	4.80	-0.48		4.30	5.28	+0.98
	Mean (n=5)	3.95	3.70	-0.25	(n=4)	4.02	4.14	+0.125
	S.D.	0.86	0.82	0.18		0.55	0.86	0.61
	Pooled Groups							
	Mean (n=8)	3.93	3.72	-0.215	(n=8)	4.032	4.035	0.003
	S.D.	0.68	0.63	0.17		0.56	0.62	0.478
				t = 3.585				t = -0.02
	Probability			p = .009				p = .98

* Data excluded from t-test comparisons.

Naeser MA, Hahn K-A K, Lieberman BE, Branco KF (2002) Carpal Tunnel Syndrome Pain Treated with Low-Level Laser and Microamps TENS. *Archives of Physical Medicine and Rehabilitation* 83: 978-988.

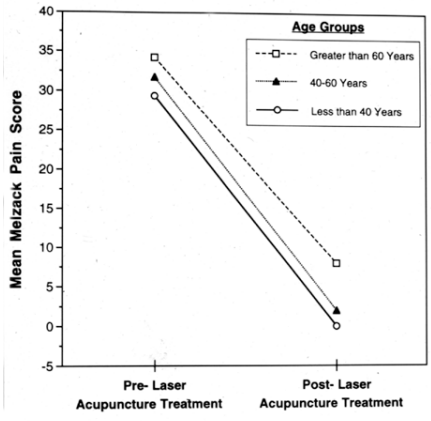


Figure 2. Mean Melzack pain scores for three separate age groups, Pre- and Post- laser acupuncture treatment. A repeated measures ANOVA showed a main effect of laser acupuncture treatment ($p < .0001$), but no effect of age group and no interaction between age group and laser acupuncture treatment.

Branco K & Naeser MA (1999) Carpal tunnel syndrome: Clinical outcome after low-level laser acupuncture, microamps transcutaneous electrical nerve stimulation, and other alternative therapies - an open protocol study. *The Journal of Alternative and Complementary Medicine* 5(1): 5-26.

Journal of Back and Musculoskeletal Rehabilitation 19 (2006) 135–140
IOS Press

Part 4. Review two LLLT Studies to Treat Fibromyalgia.

Long-term efficacy of low level laser therapy in women with fibromyalgia: A placebo-controlled study

Onur Armagan*, Funda Tascioglu, Ayse Ekim and Cengiz Oner
Osmangazi University, Faculty of Medicine, Departments of Physical Therapy and Rehabilitation, Eskisehir, Turkey

Abstract. *Aim:* To investigate the efficacy of low level laser therapy (LLLT) in fibromyalgia patients.
Materials and Methods: Thirty-four fibromyalgia patients were randomly assigned to LLLT ($n = 16$) and placebo laser groups ($n = 16$). Outcome measures included number of tender points (NTP), Fibromyalgia Impact Questionnaire (FIQ), morning stiffness, global improvement as reported on a verbal scale (VSGI), and total myalgia score. Clinical evaluations were performed before, immediately after, and six months after the treatment.
Results: In the LLLT group, significant improvement was observed in clinical parameters at the end of the treatment ($p < 0.01$). On the other hand, significant improvements were observed only in the number of tender points and morning stiffness in the placebo group ($p < 0.05$). In comparing the groups, significant improvements were detected in scores of FIQ, VSGI, and total myalgia in the active laser group ($p < 0.05$). The clinical evaluations performed after six months demonstrated improvements in the clinical parameters only in the LLLT group ($p < 0.05$). When the groups were compared with each other, significant improvements were found in the LLLT group ($p < 0.05$).
Conclusion: Our results suggest that LLLT has both short- and long-term effectiveness in the treatment of fibromyalgia.

Laser Parameters Used:

Armagan et al., 2006, Treat Fibromyalgia in Women

Wavelength: 830 nm (Near infra-red, NIR)

Laser Power: 50 mW, continuous wave, CW

Diameter of Laser Beam: 1 mm
Beam spot size: 0.0078 cm^2

Power Density: 6,410 mW/cm^2 (M. Naeser calculations)

Energy Density: 1 J/cm^2 = 0.156 sec (M. Naeser calculations)

Laser Treatment Time: 60 sec per tender spot
(2 Joules per tender spot, authors' information provided)

384.6 J/cm^2 per tender spot (M. Naeser calculations)

Total = 11 – 18 tender spots associated with Fibromyalgia pain were treated
Treatment Schedule: 1x Day, 5 Days/Week; 2 Weeks

O. Armagan et al. / Long-term efficacy of low level laser therapy in women

Table 4
The overall assessment by the patients in pretreatment, post-treatment, and month 6 time periods

	Pre-treatment	Post-treatment	Month 6
Tender point count			
LLLT group	13.69 ± 2.12	11.81 ± 1.80	12.50 ± 1.71
Placebo group	13.94 ± 2.11	12.88 ± 2.09	13.94 ± 1.88
			$p < 0.05$
Morning stiffness			
LLLT group	3.00 ± 0.63	2.38 ± 0.62	2.56 ± 0.89
Placebo group	3.06 ± 0.77	2.50 ± 0.89	3.25 ± 0.58
			$p < 0.05$
VSIQ			
LLLT group	3.44 ± 1.03	2.56 ± 0.63	3.00 ± 0.73
Placebo group	3.38 ± 0.96	3.19 ± 0.75	3.69 ± 0.70
		$p < 0.05$	$p < 0.05$
FIQ			
LLLT group	65.50 ± 9.01	58.50 ± 10.33	62.06 ± 8.99
Placebo group	65.38 ± 9.44	63.63 ± 9.59	66.94 ± 8.44
		$p < 0.05$	$p < 0.05$
Total myalgia score			
LLLT group	25.00 ± 8.66	19.50 ± 6.95	22.44 ± 6.79
Placebo group	27.56 ± 9.67	26.00 ± 8.92	28.75 ± 9.86
		$p < 0.05$	$p < 0.05$

Fibromyalgie in der Schmerztherapie

Mechanismen und Behandlungschancen durch Lasertherapie

Torsten E. Wieden, MD
Anesthesiology, Pain Therapy
Celle, Germany
wieden@schmerzpraxis-celle.de

Einführung

Die Fibromyalgie ist eine der häufigsten chronischen Schmerzerkrankungen. Schätzungen gehen für Europa von einer Erkrankungsrate zwischen 10 und 13% aus, in den vereinigten Staaten von Amerika beträgt der Anteil lediglich 2%. Befallen sind in einem Verhältnis von 8:1 vorwiegend Frauen, bei denen der Erkrankungsbeginn zumeist zwischen dem 20. und dem 35. Lebensjahr liegt.
Das Wort Fibromyalgie leitet sich mit seinen Bestandteilen *fibra* = Faser, *myos* = Muskel und *algos* = Schmerz ab und weist damit bereits in der Namensgebung auf die Lokalisation der Beschwerden hin.

Im prospektiven Schenkel der Beobachtung haben 72 Patienten eine Laserbehandlung, entweder als reine perkutane Therapie an spezifischen Akupunkturpunkten oder als kombiniertes Verfahren mit intravasaler Blutbestrahlung erhalten.

Zur Anwendung gelangte das weberneedle®-blood-System der Fa. Webermedical als LLLT mit Rotlaserbestrahlung (632,8 nm) und Grünlaserbestrahlung (532 nm) *sowie die perkutane* Applikation mittels einem weberneedle® Akupunktur-Lasernadelgerät derselben Firma, bestehend aus 6 Rotlicht- und 6 Infrarot-Laserdioden. Die Patienten erhielten jeweils 10 Akupunktur-Laserbehandlungen sowie in der betreffenden Beobachtungsgruppe mindestens drei intravasale Bestrahlungen. Die Behandlungsdauer wurde auf fünf Wochen begrenzt.

Weber Medical Laser System

Laser light emitted in various wavelengths

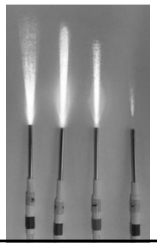
for use on Acupuncture Points,

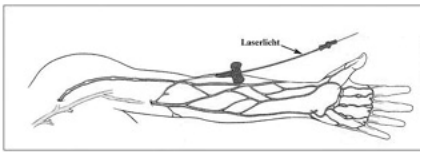
"Laser Acupuncture."

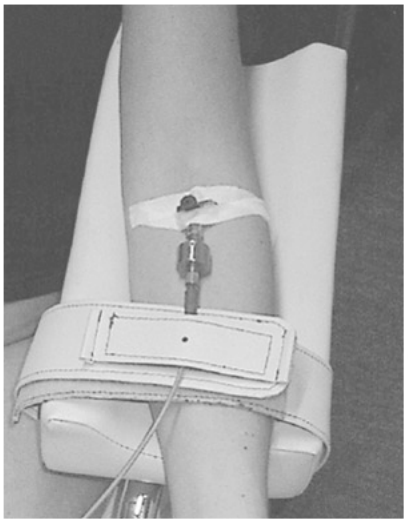
Michael Weber, MD
Lauenforde, Germany
weber@webermedical.com

Weber Medical Laser System

FIG. 3. Modern fiber-optic laser needle device with 12 channels for treating up to 12 acupuncture points simultaneously with different wavelengths.







I.V. Laser Blood Irradiation Therapy for treatment of Fibromyalgia.

Celle, Germany

Red laser light hypothesized to have ***modulating effect on leucocytes.***

These authors cite research from Russia suggesting that I.V. laser blood irradiation can promote physiological leucocytolysis similar to immuno-modulating therapies.

Michael Weber, MD
Lauenforde, Germany

Results for Treatment of Pain in Fibromyalgia. N = 72

T. E. Wieden, MD, Celle, Germany

Note: Best Results were obtained in cases treated with
10 Laser Acupuncture Treatments (Red and Infrared on Acupuncture Points)
Plus
3 I.V. Laser Therapy Sessions (Red and Green). (5 Weeks)

Beobachtungen

Exemplarisch sollen an dieser Stelle die für das Syndrom Fibromyalgie relevanten Symptome „Schmerzen", „Vegetative Störungen" und „Depression" dargestellt werden.

1. Schmerzen

Im Lauf der Behandlung nahm die durchschnittliche Schmerzstärke auf der Visuellen Analogskala (VAS) in allen Behandlungsgruppen im Vergleich zur Erstuntersuchung deutlich ab, wobei die Ausprägung der Schmerzen in der zusätzlich mit Laserlicht behandelten Gruppe die geringsten Werte zeigte.

	Beginn	Ende
MED	8,7	6,8
AKU	8,5	6
LAS	8,5	4,4
LAS+IV	8,9	2,9

MED = medikamentöse Verfahren, AKU = Nadelakupunktur, LAS = Laserakupunktur, LAS+IV = kombinierte Laserakupunktur mit intravasaler Laserbestrahlung.

I.V. Red laser, beneficial effect on Platelets and modulating effect on Leucocytes

Green laser, beneficial effect on Erythrocytes.

Results for Treatment of Depression in Fibromyalgia. N = 72

T. E. Wieden, MD, Celle, Germany

Note: Best Results were obtained in cases treated with
10 Laser Acupuncture Treatments (Red and Infrared on Acupuncture Points)
Plus
3 I.V. Laser Therapy Sessions (Red and Green). (5 Weeks)

3. Depressionsindex

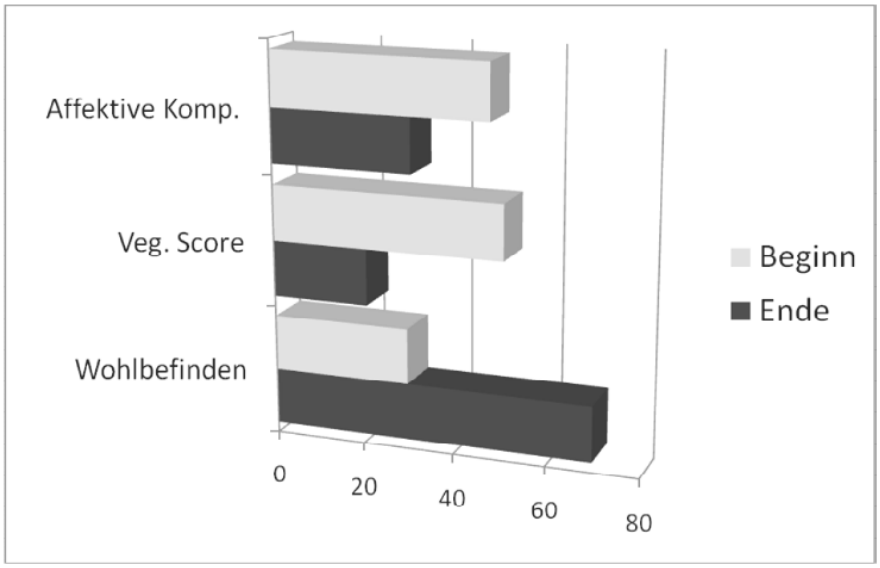
Die in Begleitung einer Fibromyalgie häufig auftretende Depression nahm insbesondere in den Gruppen mit Laserakupunktur bzw. mit Laserakupunktur und intravenöser Laserbestrahlung am deutlichsten ab.

	Beginn	Ende
MED	34	23
AP	37	24
LAS	42	12
LAS+IV	40	12

MED = medikamentöse Verfahren, AKU = Nadelakupunktur, LAS = Laserakupunktur, LAS+IV = kombinierte Laserakupunktur mit intravasaler Laserbestrahlung.

Results for Treatment of Depression in Fibromyalgia. N = 72
T. E. Wieden, MD, Celle, Germany

Laser Acupuncture *Plus* Laser Blood Irraduation



In the U.S., using the Weber Medical Laser System:

Peter T. Dorsher, MS, MD
Mayo Clinic Florida
4500 San Pablo Road
Jacksonville, FL 32224

Ph: 904-953-2823
Fax: 904-953-0276
Email: dorsher.peter@mayo.edu

Primarily treats orthopedic disorders, and uses Laser Acupuncture on skin points.

Some National and International Laser Therapy Organizations

www.naalt.org **North American Association for Laser Therapy (NAALT)**

Annual meetings are informative and educational.

www.walt.org **World Association for Laser Therapy**

www.laser.nu **Swedish Laser Medical Society**

Journals: Photomedicine and Laser Surgery
Subscription with membership in the North American Assoc. for Laser Therapy (NAALT). www.naalt.org Linked with World Association for Laser Therapy (www.laser.nu).
Lasers in Surgery and Medicine, Am. Soc. for Laser Medicine & Surgery

Team of Investigators and Collaborators

Proposed Study, Transcranial LED Tx. TBI (Not yet Funded)

VA Boston Healthcare System, JP:

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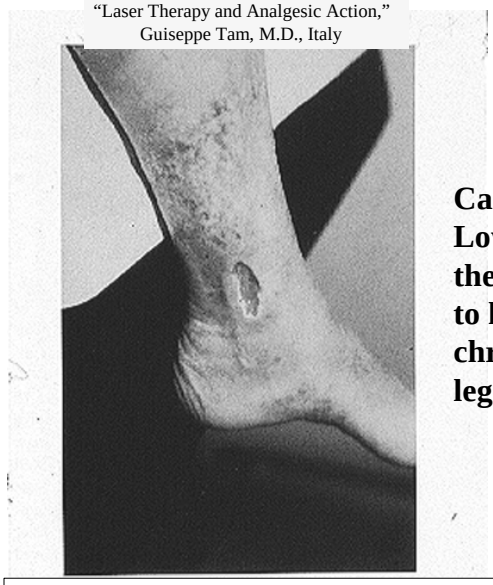
R. Rox Anderson, M.D. Director, Wellman Center for Photomedicine
Michael Hamblin, Ph.D., Cell Biologist and Biochemist, Wellman Center Photomedicine

Spaulding Rehabilitation Hospital, Boston, MA
Ross Zafonte, D.O., Chief, Rehabilitation Medicine
Harvard Medical School

Extra Slides. Additional Applications for LLLT and LED Therapies

"Laser Therapy and Analgesic Action,"
Guiseppe Tam, M.D., Italy



Case Study: Low-level laser therapy (LLLT) to heal a chronic, venous leg ulcer.

FIG. 1. A venous leg ulcer (2 cm x 0.7 cm and 0.4 cm deep) from a 62-year-old woman with hypertension is shown. All previous treatments had failed. Pulsed 904 nm, GaAr laser, once per day, for 5 days, 2 days off; repeat cycle for 12 Tx.'s..

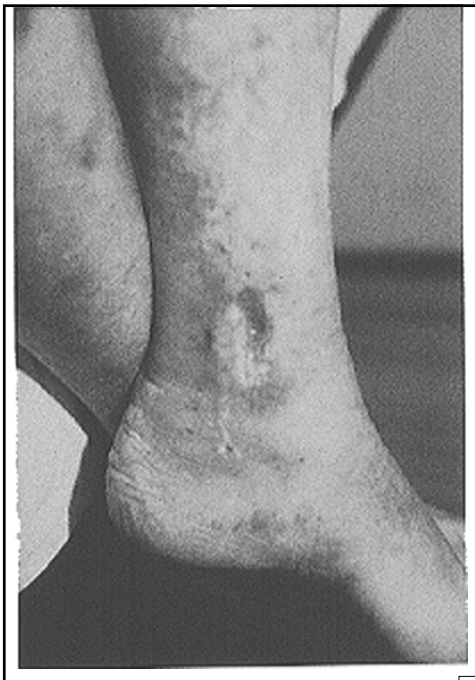


FIG. 2. After 7 applications, the depth of the ulcer was reduced.

FIG. 4. After the 12th application, the ulcer was nearly healed.

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NASA Light-Emitting Diodes for the Prevention of Oral Mucositis in Pediatric Bone Marrow Transplant Patients

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ABSTRACT

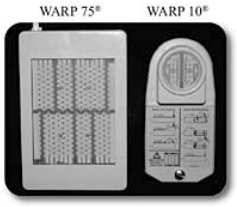
Objective: The purpose of this study was to determine the effects of prophylactic near-infrared light therapy from light-emitting diodes (LEDs) in pediatric bone marrow transplant (BMT) recipients. *Background Data:* Oral mucositis (OM) is a frequent side effect of chemotherapy that leads to increased morbidity. Near-infrared light has been shown to produce biostimulatory effects in tissues, and previous results using near-infrared lasers have shown improvement in OM indices. However, LEDs may hold greater potential for clinical applications. *Materials and Methods:* We recruited 32 consecutive pediatric patients undergoing myeloablative therapy in preparation for BMT. Patients were examined by two of three pediatric dentists trained in assessing the Schubert oral mucositis index (OMI) for left and right buccal and lateral tongue mucosal surfaces, while the patients were asked to rate their current left and right mouth pain, left and right xerostomia, and throat pain. LED therapy consisted of daily treatment at a fluence of 4 J/cm^2 using a 670-nm LED array held to the left extraoral epithelium starting on the day of transplant, with a concurrent sham treatment on the right. Patients were assessed before BMT and every 2–3 days through posttransplant day 14. Outcomes included the percentage of patients with ulcerative oral mucositis (UOM) compared to historical epidemiological controls, the comparison of left and right buccal pain to throat pain, and the comparison between sides of the buccal and lateral tongue OMI and buccal pain. *Results:* The incidence of UOM was 53%, compared to an expected rate of 70–90%. There was also a 48% and 39% reduction of treated left and right buccal pain, respectively, compared to untreated throat pain at about posttransplant day 7 ($p < 0.05$). There were no significant differences between sides in OMI or pain. *Conclusion:* Although more studies are needed, LED therapy appears useful in the prevention of OM in pediatric BMT patients.

Sample Light-emitting diode device used on the face (cheek) for the prevention of oral mucositits in pediatric bone marrow transplant patients.

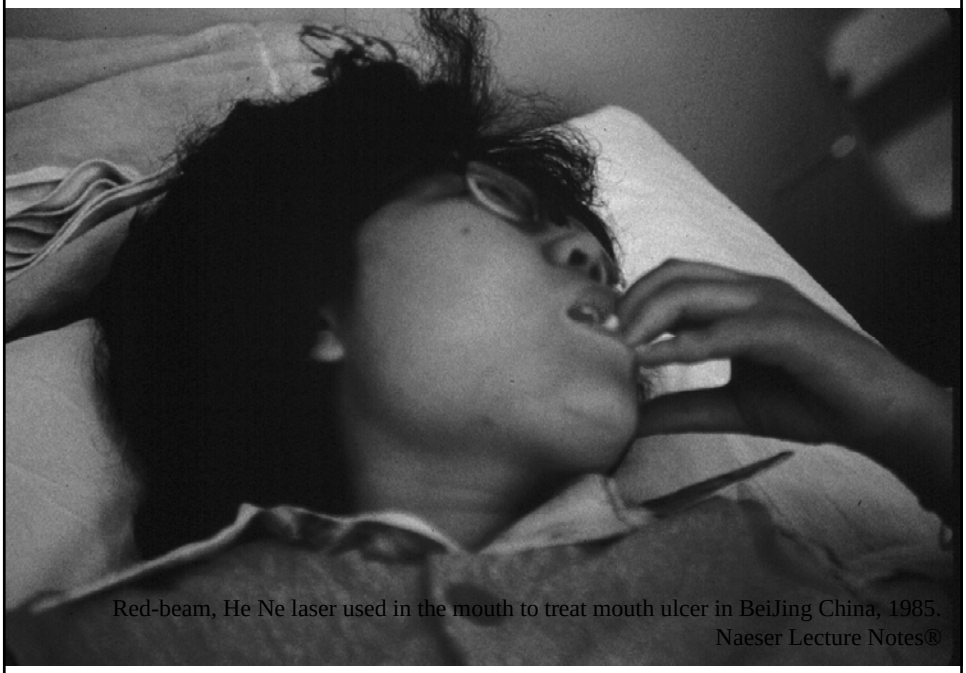
Whelan et al., 2002 (see previous slide).

Quantum WARP 75 Features:

- High intensity *60 mW/cm^2* illuminated surface produces *5 Joules/cm^2* dose in 88 seconds
- Large 75 cm^2 treatment area
- Dose accuracy controlled by an electronic timing circuit (timer) with audible end of cycle alarm
- Remains cool to the touch
- Easy to operate with one hand
- Mounted to articulated arm (upon request)
- Certified wavelength (670 nm) and power output • AC power



The WARP 75 is a larger and more powerful version of the WARP 10. System controls are located on the top panel for easy light dose delivery. Placement is directly against the skin where treatment is to occur. This is the clinical device being used in a double blind clinical trial at the Medical College of Wisconsin and University of Alabama - Birmingham Hospitals for the treatment of oral mucositis in patients undergoing bone marrow transplants. Oral Mucositis is a very painful and life threatening side effect of intense chemotherapy and radiation.



Red-beam, He Ne laser used in the mouth to treat mouth ulcer in BeiJing China, 1985.
Naeser Lecture Notes®

Treatment of Alopecia Areata with LLLT. The LLLT decreases inflammation. 50 J per cm2, per cm2 of no hair; 780 nm, 20 mW, Unilaser, Denmark.

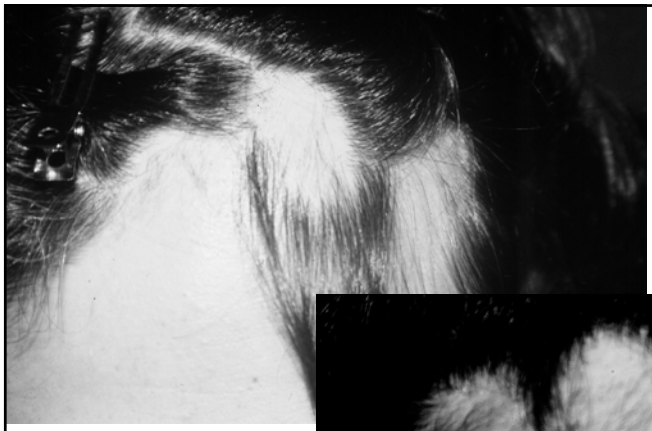
Naeser MA, Wei XB (1994) *Laser Acupuncture, an introductory textbook for treatment of pain, paralysis, spasticity and other disorders*. Boston, Boston Chinese Medicine, pp. 110 – 117.

Pre-LLLT Tx.; and post- 4 weeks, post- 8 weeks and post- 12 weeks of LLLT. Treat every other day, 3 times per week.

Naeser MA, Wei XB (1994) pp. 110 – 117

Naeser MA, Wei XB
(1994) pp. 110 – 117

New hair growth 9 Mo. after the hair began to grow back in, following 4 weeks of LLLT (50 J per cm2, per cm2 of no hair; 780 nm, 20 mW, Unilaser). She moved to another state, after she had received 3 Mo. of LLLT treatments in Boston; she received no additional LLLT



Another case study, where LLLT was used to treat the hair loss in alopecia areata.

The same laser parameters were used in this case, as in the previous case.

More effective if treated within first two years of hair loss.

Pre- LLLT Treatment

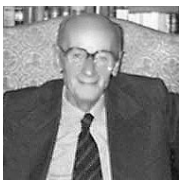
Post- 5 weeks, LLLT Treatment

Naeser Lecture Notes®

Historical timepoints

1967	Mester	Hungary	Hair growth in mice
1970s	Mester	Hungary	Wound healing in patients
1980s	Karu	Russia	Action spectrum
1980s	Pasarellla	Italy	Mitochondria & ATP
1980s	Various		Arthritis in patients
1992	Larsen	Norway	Clinical trial tennis elbow
1990s	Various		Pain relief, nerve conduction
1998	Kipshidze	Belgium	Inhibit restenosis
2001	Oron	Israel	Heart attack in animals
2002	**MicroLight**	**USA**	**FDA approval- carpal tunnel**
2003	Whelan	USA	Retinal toxicity
2004	Geuna	Italy	Peripheral nerve repair
2004	Streeter	USA	Prevent damage from stroke
2005	Anders	USA	Regenerate spinal cord rats

Endre Mester



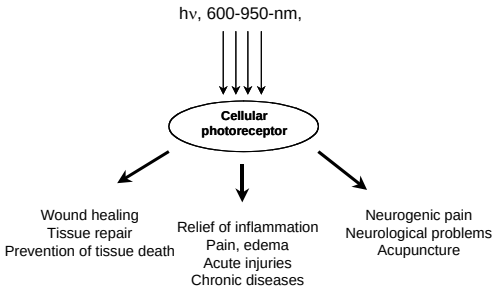
Tiina Karu

What's in a name?

Low level laser therapy
Low reactive-level laser therapy
Low intensity laser therapy
Low level light therapy
Low energy laser irradiation
Photobiomodulation
Photobiostimulation
Biomodulation
Biostimulation
Cold laser
Soft laser
Laser therapy

It is called "LOW" because a little light is better than a lot of light

First law of photobiology



Medical applications

Healing:	leg ulcers, radiation mucositis, sports injuries, dentistry, gastric ulcers
Prevention of tissue death:	myocardial infarction, stroke, retinal toxicity
Chronic orthopedic:	carpal tunnel, arthritis, tennis elbow, temporal-mandibular joint disorder
Pain relief:	trigeminal neuralgia, post-herpetic, chronic and acute traumatic pain
Edema:	lymphedema after BrCa, sports injuries
Miscellaneous:	acupuncture, tinnitus, hair regrowth, smoking cessation
Contra-indications:	directly on cancer tumor; or infection