A Skeptical Look at Low Level Laser Therapy

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Low-level laser therapy (LLLT) refers to the use of a red-beam or near-infrared laser with a wave-length between 600 and 1000 nanometers and power from 5 to 500 milliwatts. Depending on wavelength, tissues absorb energy to produce heat. LLLT lasers transfer small or very small amounts of energy into the skin. In contrast, lasers used in ablative surgery typically use 300 watts and burn the tissues they encounter.

LLLT is also referred to as cold laser therapy, low-power laser therapy (LPLT), low-intensity laser, low-energy laser therapy, and monochromatic infrared light energy (MIRE) therapy. When administered to so-called "acupuncture points," the procedure may be called "laser acupuncture." The providers include physicians, chiropractors, physical therapists, and occupational therapists, but devices are also marketed for long-term use at home.

The use of LLLT was initiated in the 1960s by a Hungarian physician named Endre Mester. The devices have been advocated for use in wound healing; smoking cessation; tuberculosis; temporomandibular joint (TMJ) disorders; and musculoskeletal conditions such as carpal tunnel syndrome, fibromyalgia, osteoarthritis, and rheumatoid arthritis. The recommended dosage, number of treatments, and length of treatment vary from one device to another.

The U.S. Food and Drug Administration classifies most LLLT devices as Class II devices as "lamp, non-heating, for adjunctive use in pain therapy" (product code NHN). Between 2002 and 2016, 44 such devices received 510(k) clearance for marketing for temporary pain relief: Acculaser Pro Low Level Laser Therapy Device; Acculaser Pro4; Axiom Biolaser LLLT Series-1; Axiom Biolaser LLLT Series-3; Bioptron Pro Light Therapy System and Bioptron Compact III Light Therapy System; Collagentex Rx-1; Diobeam 830; Elite Electromed L.I.T.E. 4/1; Erchonia's Allay, Emerge, EML Laser, EML Laser; Evri, Mis-Ac Derma Scanner, Pl2000, Pi5000, Pi Touch, and TH1 Laser; Excalibur IV Light Therapy System Model SGEX4-001; Excalibur Light Therapy System Model SGLEX-04-001; GRT Lite Model 8-A; Lapex 2000; Laser Helmet, Lasertouchone; Lazrpulsr 4x; Ld-I 75 And LD-I 200; LEP2000 Therapy System; Lightstream Low Level Laser; Luminex LL Laser System; Lx-100 Hair Growth Stimulation System; Medx LCS Laser Series; Microlight 830 Laser System; NMA 1052 Console System With NMA 100 Laser Accessory; Omega Excel/XP Laser System; Power Laser 90; QLaser System; Quantum Light Therapy System; Sunetics Clinical Bio-Stimulation Laser; Theralase TLC-2000 Therapeutic Medical Laser System; Thor DDII 830CL3 Laser System; Tlc-2000 Therapeutic Medical Laser System; and Trilumina Therapeutic Laser System. Most of the clearances were for symptoms related to wrist pain due to carpal tunnel syndrome, but a few mentioned temporary relief of muscle stiffness, minor arthritis pain, and/or temporary increase in local blood circulation. The FDA has also cleared one device, the LTU-904 Portable Laser Therapy Unit as "light, lymphedema reduction, low energy" (product code NZY).

Government Enforcement Actions

The most aggressively promoted LLLT product appears to be the Anodyne Therapy System, which has professional and home versions. It is marketed by Anodyne Systems, LLC, of Tampa, Florida, which also has operated as Restoration Health. It is marketed for LLLT even though the FDA classifies it as an infrared heat lamp (product code LDY). The FDA cleared it (under the name Spectropad) in 1994 for "relief of minor muscle and joint pain and improvement of superficial circulation." However, for several years, the company's Web site suggested that it could do more. In 2005, after conducting an inspection, the FDA sent the company a warning letter stating:

> Our inspection determined that your product labeling and internet website promote the Anodyne Therapy System for use in the treatment of wounds and ulcers, loss of protective sensation, gait and balance impairment, and other Diabetic Peripheral Neuropathy conditions, as well as conditions associated with Non-diabetic Neuropathies. Your company is also promoting the Anodyne Therapy System for the treatment of conditions including, but not limited to, soft tissue injuries, Carpal Tunnel Syndrome (CTS), and lymphedema. According to our records, however, you do not have marketing clearance from FDA to distribute into interstate commerce the Anodyne Therapy System for these uses.
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> . . . . Because you do not have marketing clearance from the FDA for these new intended uses, marketing the Anodyne Therapy System with these claims is a violation of the law [2].

In 2015, Anodyne's Web site stated that its device was prescribed by more than 11,000 physicians and had been the subject of 19 published studies [1]. Studies also exist for a few other devices. The scientific consensus is that no LLLT has been proven more effective for pain than standard forms of heat delivery. Some benefits have been reported, but the studies have been too small and/or too short to draw firm conclusions. The best-designed study of diabetic patients with sensory nerve impairment of the feet found that 90 days of Anodyne therapy at home brought about no more improvement in peripheral sensation, balance, pain, or quality of life than sham therapy [3].

One FDA-cleared LLLT device—the QLaser—has been promoted with curative claims that resulted in civil and criminal prosecution. The primary marketer, Robert L. Lytle (better known as Dr. Larry Lytle), had begun manufacturing and distributing low-level laser devices in 1997, shortly before the South Dakota Board of Dentistry had revoked his dental license for fraud and substandard patient care. In 2014, a federal complaint charged that Lytle, doing business as QLasers PMA and 2035 PMA, had marketed a dozen devices with illegal claims that they could treat "over 200 different diseases and disorders," including cancer, cardiac arrest, deafness, diabetes, HIV/AIDS, macular degeneration, and venereal disease. However, court documents indicate that although the FDA obtained a permanent injunction [4], Lytle continued selling the devices to and through other distributors. In 2017, he and two of his main distributors were charged with conspiracy in connection with the sale of QLaser devices [5,6]. All three pleaded guilty and recived prison sentences [7]

Insurance Company Critiques

Aetna, CIGNA, and the Center for Medicare and Medicaid Services (CMS), have published detailed critiques of Anodyne's data and other published studies and explain why they do not cover LLLT.

- Aetna considers treatment with low-level infrared light (infrared therapy, Anodyne Therapy System) experimental and investigational for the treatment of acne, back (lumbar and thoracic) pain, Bell's palsy, central nervous system injuries, chronic non-healing wounds, diabetic peripheral neuropathy, ischemic stroke, lymphedema, neck pain, osteoarthritis, Parkinson's disease, retinal degeneration, and stroke because of a lack of adequate evidence in the peer-reviewed published medical literature regarding the effectiveness of infrared therapy for these indications [8].
- CIGNA concludes: Low-level laser therapy (LLLT) has been proposed for a wide variety of uses, including wound healing, tuberculosis, and musculoskeletal conditions such as osteoarthritis, rheumatoid arthritis, fibromyalgia and carpal tunnel syndrome. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that LLLT is effective for these conditions or other medical conditions. Large, well-designed clinical trials are needed to demonstrate the effectiveness of LLLT for the proposed conditions [9].
- CMS has determined that there is sufficient evidence to conclude that the use of infrared devices is not reasonable and necessary for treatment of Medicare beneficiaries for diabetic and non-diabetic peripheral sensory neuropathy, wounds and ulcers, and similar related conditions, including symptoms such as pain

arising from these conditions. Therefore, we are issuing the following National Coverage Determination. The use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy (MIRE), is not covered for the treatment, including symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of skin and/or subcutaneous tissues in Medicare beneficiaries [10].

A few other insurance companies have published brief statements with the same conclusion.

The Bottom Line

At this writing, the bottom line appears to be that LLLT devices may bring about temporary relief of some types of pain, but there's no reason to believe that they will influence the course of any ailment or are more effective than standard forms of heat delivery.

References

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