Summary of Clinical Studies on Low Energy Photon Therapy for Pain and Carpal Tunnel Syndrome Management

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Low Energy Photon Therapy (LEPT) is a photo-therapeutic modality for pain relief and soft tissue healing acceleration that involves the irradiation of tissue with monochromatic light at intensities that do not cause thermal changes or ionization in tissues. Clinical studies reflected in this review have been performed in Canadian universities, hospitals and clinics during years 1989-2002. This clinical research has been supported by Canadian granting agencies (NRC and DoD of Canada and others). All studies have been performed using a professional system with different single and cluster multiple-sources probes at wavelengths of 660nm, 830nm, 880nm, and 990nm with a range of frequencies of 1-200 Hz, or continuous wave mode. Since 1989 we created three generations of LEPT clinical protocols (using light emitting diodes) for pain relief and carpal tunnel syndrome management. First generation of LEPT clinical protocols had been tested in several prospective, open protocol clinical and case studies involving over 250 subjects with different musculoskeletal and neuromuscular pathologies. Full resolution or significant improvement of symptoms was achieved in 55-75% of cases depending on the pathology. We conducted a correlation analysis of immediate pain relief (after 1-2 sessions of LEPT) and cumulative pain relief after 10 sessions using the results of these clinical studies. A strong positive correlation was found between immediate and cumulative (after 10 sessions) pain relief. This finding encouraged us to concentrate our effort on the optimization of LEPT protocols for immediate (after 1-2 sessions) pain relief. In early nineties we embarked upon investigation of the most crucial aspects of photon-biotissue interaction and LEPT dosimetry for pain relief and soft tissue healing. As a result of this basic research, we created next generations of integrated LEPT clinical protocols for pain relief and soft tissue healing. These integrated clinical protocols consist from several specific protocols that are applied in physiologically justified sequence one after another. Each specific LEPT protocol is hypothesized to improve a specific for this particular protocol soft tissue pathology, e.g., to relieve muscle spasticity, to increase cellular energy and reduce ischemic pain, to decrease swelling, to reduce pain and inflammation, etc. Integrated LEPT clinical protocols were further optimized in clinical settings

(involving over 1500 patients) using biofeedback (surface EMG, Whole Blood Chemiluminescence, Laser Doppler Flowmeter, etc.).

An integrated LEPT clinical protocol efficacy for the recovery of the neck extensor muscle (NEM) strength and sleep improvement in subjects after acute whiplash injury has been tested in a randomized controlled clinical trial involving 54 subjects. By the end of this 8-week clinical trial, statistically and clinically significant improvement in the NEM strength and sleep pattern was observed in the LEPT group as compared to conventional therapy (neck exercises and manipulations) group.

The efficacy of integrated LEPT clinical protocol versus ultrasound and placebo LEPT for pain relief has been tested in a recent controlled, randomized, comparative double blind clinical trial. 75 subjects that suffered subacute (2 weeks-6 months duration) and chronic (>6 months duration) pain in soft tissue surrounding joints were randomly allotted to the following three groups: Group 1 received LEPT; Group 2 received Ultrasound; and Group 3 received placebo LEPT. Each subject received 2 treatments of selected in accordance with the random number modality during three consecutive days. Pain rating by 10-cm visual analog scale (VAS) was taken prior to and after each treatment. All required blindness procedures were strictly followed in this study. Statistical analysis revealed that LEPT had superior (4-fold) efficacy for pain relief as compared to ultrasound, and to placebo. In particular, in a group treated with LEPT mean pain VAS dropped by 40%, while in the ultrasound group a moderate pain reduction of 10% was not statistically significantly different from pain relief in the placebo group (by 14%). Another double blind clinical trial with a similar design on the LEPT efficacy for pain relief in 22 subjects who suffered from acute (<2 weeks duration) and subacute symptoms has been accomplished. LEPT efficacy (pain relief by 53.% after 2 treatments) was found to be superior to ultrasound (by 31.6%) and placebo (by 20%).

A prospective open protocol study on the efficacy of LEPT for symptom relief in patients with carpal tunnel syndrome (CTS) resulted in full resolution of symptoms in 15 out of 21 (71.4%) patients who suffered chronic CTS. The LEPT protocol that was used in this study appeared to be effective for symptom relief, however, it did not produce consistent clinically significant improvement of nerve conduction test. The LEPT protocol had been improved and tested in a recent prospective open protocol clinical trial involving 19 patients with 34

hands affected by CTS. In this study, a normalization of mean median nerve motor distal latency (from 4.68msec, range 4.2-6.0msec to 3.9msec, range 3.5-4.2msec) was observed after a course of LEPT (10-24 sessions). Patients also experienced pain relief by 70% and improvement of night sleep interruption by 79%. The results of the study were found to be statistically significant.

Last several years, we carried on jointly with Canadian hospitals and clinics a series of prospective open protocol studies on the LEPT efficacy for different types. These studies produced consistent statistically significant results of 39-56% of pain relief after 2 LEPT sessions including those patients who did not respond previously to conventional therapies.

We developed integrated LEPT protocol that could be administered immediately after trauma. Timing of LEPT administration after an acute injury appears to be a critical factor affecting the rate of recovery. Anecdotal case studies suggest that early intervention (within 24 hours after the injury) with LEPT could induce pain relief of 50-100% after 2 LEPT treatments. This pain relief is accompanied by inflammation and swelling reduction and improvement of ROM and weight-bearing. If these anecdotal data are proven in a rigorous double blind study, it could change a current paradigm of acute trauma management.

The above body of clinical evidence suggests that LEPT has substantial potential to become an effective treatment modality for pain, acute trauma and carpal tunnel syndrome management.