



Research Article

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# Clinical Effectiveness and Safety of a Combined Photobiomodulation and Electrical Stimulation Device for Chronic Pain: Evidence of Rapid Improvement Within a Two-Week Treatment Course

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## Abstract

**Background:** Chronic pain is a multifactorial condition affecting over 50 million U.S. adults and remains inadequately controlled by standard pharmacologic therapies due to limited efficacy, systemic side effects, and growing emphasis on opioid-sparing strategies. Multimodal biophysical therapies (i.e., photobiomodulation (PBM) and electrical stimulation) target distinct physiological pathways involved in pain, inflammation, micro-vascular function, and neuromodulation. Although each modality has demonstrated independent benefit, their simultaneous integration within a single device has been insufficiently studied.

**Objective:** To evaluate the real-world clinical impact of an integrated PBM/PEMF/ electrical stimulation device (Neurolumen®) on pain intensity, diurnal pain variability, and sleep patterns in adults with chronic musculoskeletal, neuropathic, or mixed-etiology pain.

**Methods:** This prospective observational study followed carefully screened participants (n=68) over a two-week, ten-session treatment course. Pain was captured using 24-hour hourly diaries on treatment days, while sleep patterns and physiological parameters were recorded during office visits. Outcomes included change in baseline-to-post-treatment pain, responder status (≥2-point reduction), strong response (≥4-point reduction), diurnal pain trends, lowest and highest pain episodes, sleep and duration and occurrence. Analyses were descriptive.

**Results:** Across analyzable diaries, approximately two-thirds of participants experienced clinically meaningful improvement, with a mean reduction of ~3 points on the 0-10 scale and frequent strong responses. Notably, these improvements occurred within only two weeks of treatment, demonstrating a rapid therapeutic effect. Diurnal analysis revealed consistent midday pain peaks with evening and night reductions, while therapy stabilized these fluctuations and produced extended low-pain intervals (Level 1-2 lasting up to 24 hours), most commonly during days 7-14. Sleep duration was stable or improved, and physiological parameters demonstrated favourable shifts, including immediate 9.6% increases in vibration sensitivity. No serious adverse events were observed, and tolerability was high. Placebo participants (n=3) showed minimal engagement and no meaningful improvement.

**Conclusions:** Integrated multimodal biophysical therapy produced rapid, clinically significant improvements in pain and sleep, stabilized circadian pain variability, and demonstrated favourable physiological responses within a short two-week treatment window. The safety, tolerability, and magnitude of benefit support the clinical readiness of this technology as a non-pharmacologic, opioid-sparing intervention for chronic pain management. Larger, well-controlled randomized trials, stratified by pain phenotype and optimized using circadian timing principles, are warranted to refine dosing, confirm durability, and expand generalizability.

**Keywords:** Chronic pain, Photobiomodulation, Electrical stimulation, Multimodal analgesia, Circadian pain modulation



## Introduction

Chronic pain is a pervasive and complex clinical condition affecting more than fifty million adults in the United States and hundreds of millions globally, spanning musculoskeletal, neuropathic, inflammatory, and postsurgical etiologies [1]. Individuals commonly present with multifocal pain (i.e., low back pain, knee and hip osteoarthritis, neck and shoulder disorders, radiculopathy, limb pain, migraines, and postoperative or post-traumatic pain), reflecting the heterogeneous and multifactorial nature of chronic pain syndromes [2]. These conditions frequently lead to substantial functional impairment, sleep disruption, psychological distress, reduced mobility, and diminished quality of life. Despite widespread use of pharmacologic therapies such as Nonsteroidal Anti-inflammatory Drugs (NSAIDs), opioids, anticonvulsants, and antidepressants, treatment outcomes remain suboptimal [3]. Analgesic medications often yield only partial relief and are further limited by systemic side effects, tolerance, drug-drug interactions, and, in the case of opioids, risks of dependence and overdose [4]. The urgent need for safer, non-pharmacologic interventions has driven increasing interest in biophysical therapies capable of modulating pain without systemic exposure.

The biological mechanistic underpinnings of chronic pain are multifaceted, involving maladaptive neuroplasticity, central sensitization, local inflammation, mitochondrial dysfunction, impaired microvascular circulation, neuromuscular imbalance, and autonomic dysregulation [5]. Given this complexity, single-mechanism treatments may fail to adequately address the underlying drivers of persistent pain. Multimodal, energy-based therapies such as low-level laser therapy (LLLT), photobiomodulation (PBM), pulsed electromagnetic field therapy (PEMF), and electrical stimulation, offer the potential to target multiple physiological domains simultaneously. LLLT and LED-based PBM deliver red and near-infrared light which enhances mitochondrial respiration, ATP synthesis, and nitric oxide release, improving cellular metabolism and microvascular perfusion while reducing oxidative stress and inflammatory mediators [6]. PEMF therapy exerts complementary effects by inducing microcurrents that stabilize cell membrane potentials, enhance ion flux, promote angiogenesis, and upregulate growth factors involved in tissue repair and neuromuscular recovery [7]. Electrical stimulation provides analgesia through activation of large-diameter afferent fibers, engagement of spinal gating mechanisms, and increased release of endogenous opioids and monoamines, thereby suppressing nociceptive signaling at multiple levels of the nervous system [8]. When used concurrently, LLLT/PBM, PEMF, and electrical stimulation provide a synergistic therapeutic platform capable of addressing the metabolic, inflammatory, vascular, and neurophysiological contributors common across diverse pain conditions. Although each modality has demonstrated efficacy independently, far fewer studies have evaluated their combined, simultaneous application within a single device. The integrated approach may offer greater therapeutic impact than any component alone, particularly for complex pain syndromes involving overlapping musculoskeletal and neuropathic mechanisms.

The present study was designed to systematically evaluate the clinical effects of this multimodal biophysical therapy across a broad range of chronic pain presentations, including spinal pain, peripheral joint pain, soft tissue injury, neuropathic pain, and mixed-etiology conditions. Treatment outcomes were assessed using longitudinal hourly pain diaries, lowest and highest pain episodes, and sleep metrics. By capturing both acute and cumulative effects of therapy, the study aimed to characterize real-world treatment trajectories, identify responder profiles, and determine the potential role of integrated LLLT/PEMF/ electrical stimulation therapy as a non-pharmacologic strategy for managing chronic pain across diverse clinical indications.

## Methods

### Study Design and Participants

This study was a prospective, observational analysis conducted to evaluate the effects of multimodal e-photonic therapy on pain intensity, sleep patterns, and physiological parameters in adults diagnosed with chronic musculoskeletal, neuropathic, or mixed-etiology pain conditions. Individuals were included if they provided at least, one completed daily pain diary or sleep log during the treatment period. Patients who withdrew were assigned to placebo control, or who did not return diaries were retained for descriptive accounting but excluded from primary effectiveness analyses.

After obtaining informed consent, 68 adult patients suffering from chronic pain (at least 3 months) were enrolled in the two-week study. A widely diverse pain location and various types of pain syndromes were represented. Three patients received placebo treatment in a double-blind manner by placement of the wrap assembly over the painful location without e-photonic therapy. All other patients received ten daily 30-minute treatments with a pre-treatment numerical pain assessment and the same post treatment evaluation.

A simple wrap assembly uniquely engineered to incorporate microprocessor-controlled driver circuitry to deliver precisely coordinated energy through multiple electro-current and photonic transmission components was used. A broad spectrum of energy wavelengths utilizing 24 light emitting diodes, 12 low level lasers and 8 surface conductive adhesive pads were used to create the desired tissue bio-modulation response. The e-photonic treatment device is composed of several integrated structural components designed to deliver therapeutic light and electrical stimulation. It is powered by a 3.6-volt lithium-ion battery and recharged through a universal 220/110 VAC charger that outputs 9 VDC at 1.5 A. The wrap assembly, secured with Velcro and adhesive pads, houses multiple light-emitting elements, including two 808 nm laser diodes providing 60mW of output power, two red LEDs operating at 660 nm with 15mW output, and two infrared LEDs at 904 nm producing 22mW. In addition to photonic components, the device incorporates a T.E.N.S. unit designed for a 500-550 ohm load, delivering 2 Hz stimulation with a maximum output current of 100 mA, a 75 VDC pulse voltage, and a 100  $\mu$ s biphasic pulse width. Together, these components form the functional structure of the wrap-style

e-photonic therapy system.

All active-treatment participants received multimodal therapy consisting of low-level laser, LED PBM, and electrical stimulation via the Neurolumen® system. Treatment sessions were administered according to manufacturer protocols. Placebo participants received identical devices without active energy output. Each participant completed up to ten treatment visits, and pain, sleep, and physiological metrics were recorded during and/or after each visit.

Hourly pain intensity was recorded using a 0-100 numeric rating scale across a 24-hour period for every study day with a completed diary. Baseline pain and post-treatment pain at follow-up were extracted from participants' daily diary entries. In addition, diaries documented each participant's lowest pain level, highest pain level, duration of pain episodes, and the day on which these extremes occurred.

### Sleep and Physiological Data Collection

Sleep logs were completed during all 10 treatment visits and included:

1. Sleep occurrence (yes/no),
2. Total sleep hours,

Participants were also encouraged to report sleep, including nights with zero or limited (<2 hrs per night) sleep hours. The primary outcome was change in pain intensity, defined as the difference between Pain 0 and Pain [1].

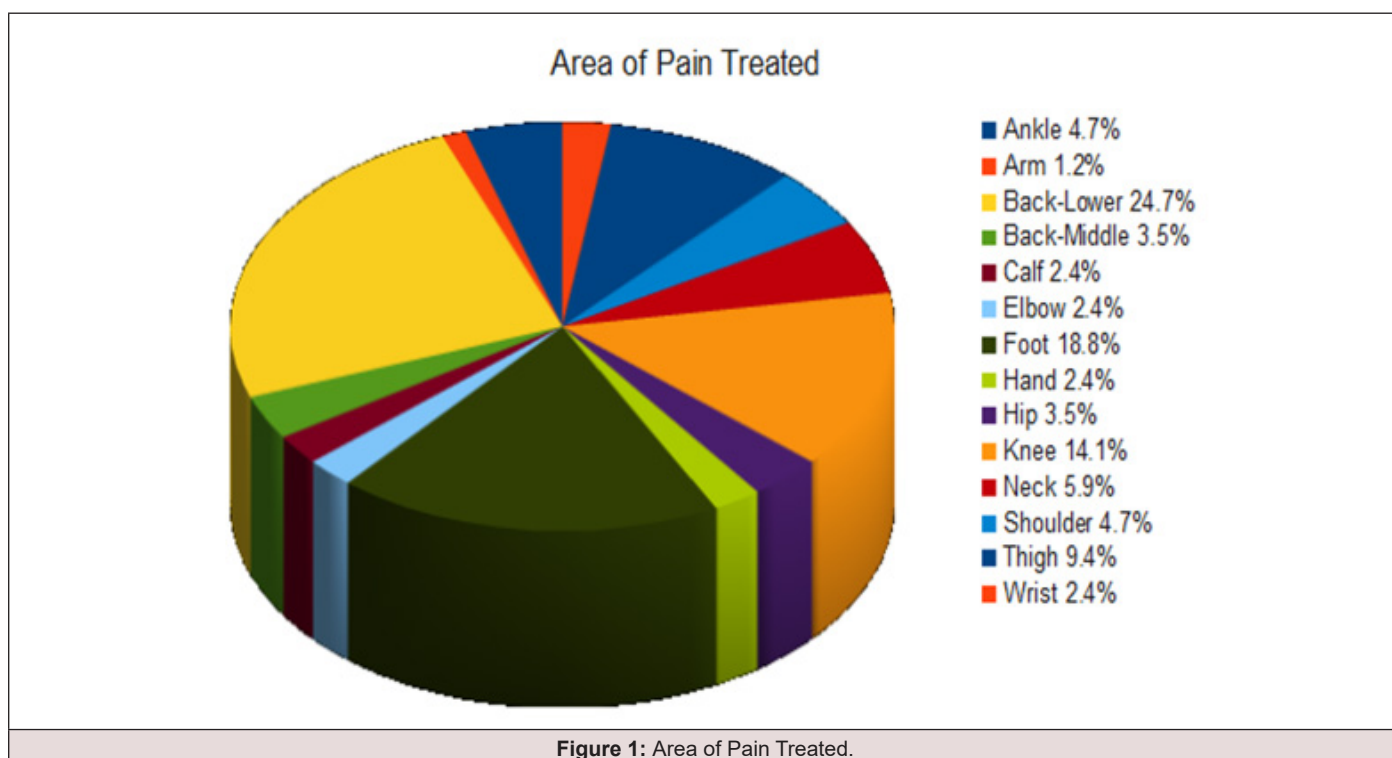
Secondary outcomes included:

- hourly pain trends across the 24-hour cycle,
- duration of low- and high-pain episodes,
- responder status ( $\geq 2$ -point improvement) and strong responder status ( $\geq 4$ -point improvement),
- sleep occurrence and sleep duration patterns across of-fice visits.

**Safety and Adverse Events:** Participants were monitored for skin irritation, muscle soreness, or discomfort during and after each session. No serious adverse events were recorded.

### Statistical Analysis

All analyses were conducted using standard descriptive and comparative methods. For pain scores and sleep variables, we first summarized data using means, standard deviations, medians, and ranges for continuous variables and counts with percentages for categorical variables (e.g., responder status, sleep yes/no). Within-patient change in pain from baseline to post-treatment was calculated as baseline - follow-up. Patients were classified as responders if they demonstrated a  $\geq 2$ -point reduction in pain and strong responders if reduction was  $\geq 4$  points. For patients with complete paired measurements, we compared baseline and post-treatment pain. Hourly pain data were averaged within prespecified time blocks (early morning, midday, evening, overnight) to describe diurnal patterns. Sleep hours and the proportion of nights with any sleep were summarized per patient and descriptively compared between responders and non-responders. No formal adjustment for multiple comparisons was performed given the exploratory nature of the study.



Pain treatment needs were concentrated primarily in the lower extremities and lumbar region, consistent with the prevalence of musculoskeletal and neuropathic conditions in the study population. Figure 1 illustrates the proportional distribution of anatomical regions treated across the study cohort. The most frequently treated site was the lower back (24.7%), followed by the foot (18.8%), knee (14.1%), and thigh (9.4%). Other commonly treated areas included the neck (5.9%), ankle (4.7%), shoulder (4.7%), arm (1.2%), middle back (3.5%), calf (2.4%), elbow (2.4%), hand (2.4%), hip (3.5%), and wrist (2.4%) (Figure 1).

Table 2 provides a broad view of pain severity across all patients and all recorded hourly time points, offering insight into the general intensity and variability of pain within the study population. The mean pain score of 58.7 indicates that, on average, patients experienced pain at a moderate-to-high level throughout the monitoring period, while the median score of 57 suggests that half of all recorded values clustered just below this average, reinforcing the consistency of moderate pain levels across the dataset. The standard deviation of around 20.6 reflects substantial variability in pain intensity between patients and across hours, highlighting

that while many participants remained within a moderate range, others experienced significantly higher or lower levels. This range is further illustrated by the minimum observed pain score of 10, representing the lowest pain reported among all individuals and timepoints, and the maximum score of 129, indicating extreme pain at the upper end of the spectrum. Together, these metrics depict a cohort with generally high pain burden but considerable inter-individual fluctuation, underscoring the complexity and heterogeneity of chronic pain experiences within the study.

Table 1 summarizes the baseline characteristics of participants who began the study compared with those who completed it. The two groups were highly similar across all measured variables, including age, sex distribution, BMI, and the prevalence of common comorbidities such as hypertension, arthritis, neuropathy, and chronic musculoskeletal conditions. Diagnostic categories (e.g., pain area or condition), were proportionally balanced between groups. The close alignment of these characteristics indicates that attrition did not introduce meaningful demographic or clinical bias, supporting the internal validity of subsequent outcome comparisons.

Table 1: Characteristics of Patients in Study Group.

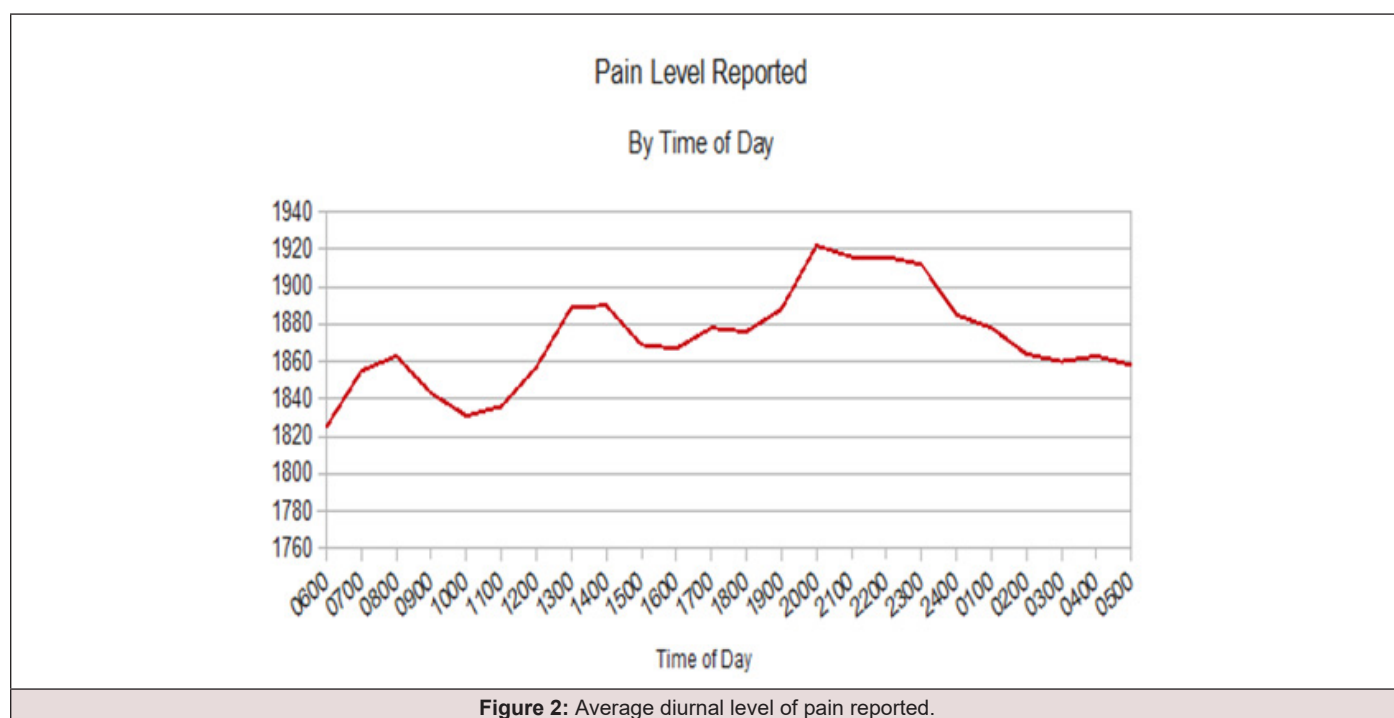
	Began Study	Completed Study
N	68	51
Age (mean)	57.5	59.1
Male	32	25
Female	38	30
Hypertension	12	11
BMI (mean)	30.2	30.4
Arthritis	2	2
Fibromyalgia	2	2
Migraine	1	0
Neuropathy	12	8
Foot & Leg Pain	26	24
Back Pain, Sciatica	26	17
Devices	1	1
Lupus	1	1
Stroke	1	0
Lymphedema	1	0
Other	20	17

Table 2: Overall pain score summary.

Metric	Value
Mean Pain Score	58.7
Median Pain Score	57
Standard Deviation	20.6
Minimum Value	10
Maximum Value	129

Figure 2 illustrates an analysis of pain trends across all hourly timepoints reveals a distinct diurnal pattern characterized by moderate early-morning pain, a pronounced midday escalation, and a gradual decline into the late evening and overnight hours. Specifically, average pain scores in the early morning (06:00-10:00) remain within the 50-55 range, indicating moderately elevated discomfort upon waking. Pain intensifies markedly during the midday interval (11:00-17:00), peaking between 62 and 68, which represents the highest sustained period of discomfort across the full 24-hour cycle. This midday peak may reflect increased physical activity, cumulative fatigue, or circadian modulation of inflammatory or neuropathic processes. By the evening (18:00-22:00), pain scores decrease slightly to approximately sixty, followed by a further reduction overnight (00:00-05:00) to around fifty-five, suggesting

that rest and reduced functional demand contribute to symptom relief. Patterns of patient-specific stability further highlight heterogeneity in pain regulation. Several individuals exhibited highly stable pain trajectories with minimal hourly deviation, indicating predictable symptom profiles and potentially more treatment-responsive or less volatile pain mechanisms. Conversely, others displayed substantial instability, with fluctuations of  $\pm 20$ -40 points, reflecting more labile or refractory pain states. Several patients warrant heightened clinical attention: those with consistently severe average pain levels above 90 represent a high-burden subgroup with persistent extreme pain, while individuals showing extreme variability exceeding forty points or sudden acute pain surges may be experiencing episodic exacerbations requiring targeted intervention.



**Figure 2:** Average diurnal level of pain reported.

The baseline pain levels across the cohort reveal a population experiencing substantial discomfort prior to treatment, with the highest baseline scores reaching 10 out of 10 in multiple patients. These individuals entered treatment already at the threshold of extreme pain, reflecting severe underlying pathology or long-standing chronic conditions. At the lower end, baseline pain values were reported at 4 out of 10. The average baseline pain was approximately 7.5/10, confirming that the study population was, overall, moderately to severely impaired at intake. Following treatment, a meaningful proportion of participants demonstrated measurable improvement in pain after only two weeks of treatment. Several patients improved by  $>4$ , indicating strong clinical improvement suggestive of a robust therapeutic response. The Nearly 40% of patients experienced 1-3 point reductions, representing mild to moderate improvement, which is still clinically relevant, particularly in chronic pain populations. Approximately 10% of patients

showed no change, a pattern commonly observed in individuals with neuropathy or fixed structural conditions where pain may be more resistant to intervention. A small subset ( $n=3$ ) experienced worsening pain, although such cases were relatively rare. Among the patients who did improve, the average reduction was roughly 3.1 points ( $\sim 5\%$ ), demonstrating a generally positive treatment effect with clinically meaningful decreases in pain severity for a substantial portion of the cohort.

During treatment, the lowest recorded pain levels represent the periods of greatest relief for participants and provide insight into how effectively symptoms were managed over time. Notably, many patients achieved level 1 or level 2 pain for 24 continuous hours, indicating strong and sustained therapeutic benefit. These extended low-pain episodes frequently occurred between Days 7 and 14, suggesting that the effectiveness of the treatment may



increase cumulatively as therapy progresses. Patients with conditions such as neuropathy, spinal stenosis, and chronic disc disease often demonstrated the longest durations of minimal pain, which is particularly meaningful given the chronic and typically resistant nature of these diagnoses. Examples of strong low-pain episodes include one patient who reported level 2 pain for 20 hours on Day 4, and several others who experienced full 24-hour relief intervals. Importantly, patients who achieved these prolonged low pain windows typically also showed meaningful reductions from baseline to post-treatment pain scores, reinforcing the connection between sustained relief episodes and overall clinical improvement.

During treatment, the highest pain levels recorded across participants indicate the presence of significant flare-ups, reflecting moments of intensified discomfort despite ongoing therapy. The most common peak pain levels fell within level 6 to Level 7, suggesting that moderate to severe spikes were frequently encountered in this population. More serious flare-ups (i.e., levels 8 through 10) were documented in approximately twenty patients, highlighting a substantial subgroup with severe episodic pain. Several individuals experienced extended durations of high-intensity pain, emphasizing the chronic and resistant nature of their underlying conditions. For example, one patient reported a level 10 flare lasting 19 hours on Day 14, while another also reached level 10 for 11 hours on Day 3, and another sustained level 10 pain for 10 hours on Day 1. Other significant episodes included a patient who experienced level 9 pain continuously for 24 hours on Day 9, and a patient, who maintained level 8 pain for a full 24 hours on Day 12. Even at slightly lower intensities, prolonged episodes were notable, such that one patient recorded level 6 pain for 20 hours on Day 13. These extended high-pain intervals were predominantly seen in individuals with structural or degenerative conditions, such as disc disease, prior surgeries, and knee replacements, suggesting that anatomical impairment may contribute to the persistence or severity of flare-ups despite treatment.

The placebo group (n=3) showed a consistent pattern of minimal engagement and limited therapeutic response. Most placebo participants did not return diaries, resulting in insufficient data to track daily fluctuations or identify meaningful trends in their pain experiences. Among the few with partial information, no substantial reduction in pain levels was observed, and none demonstrated the marked improvements seen in several actively treated patients. This lack of measurable progress aligns with expectations for a placebo cohort, reinforcing that the therapeutic effects documented in other participants are unlikely to be attributable solely to psychological or expectancy-driven influences. The limited engagement from placebo subjects also highlights challenges in adherence and data completeness within this subset.

Patients with acute injury recovery, radiculopathy, degenerative disc disease, post-surgical pain, and carpal tunnel had the best response. Several patients demonstrated both a substantial reduc-

tion in pain intensity and extended periods of sustained low pain, indicating robust treatment responsiveness across a range of clinical conditions. Individuals with acute or structural injuries showed particularly strong effects. For example, a patient with a broken ankle improved from a pain score of 9 to 0 and experienced a Level 2 pain episode lasting 24 hours on Day 13. Similarly, a patient with lower back pain showed a drop from 9 to 1, accompanied by 24 hours of Level 4 pain on Day 4. Those with degenerative conditions also exhibited notable improvements: a patient with degenerative disc disease improved from 10 to 1 and achieved 22 continuous hours of Level 5 pain relief on Day 4. Patients with neuropathic etiologies responded as well, such as the individual with neuropathy affecting the hips, pelvis, and legs, who improved from 8 to 0 with an 11-hour Level 2 low-pain episode on Day 13. Upper-extremity conditions also showed favourable outcomes; a patient with carpal tunnel syndrome improved from 6 to 2 and recorded a full 24-hour low-pain interval on Day 14. Likewise, a patient with chronic lower back pain improved from 7 to 1 and experienced 24 hours of low pain on Day 14. Together, these cases highlight the potential of multimodal therapy to produce both immediate and sustained relief across musculoskeletal, neuropathic, and degenerative pain conditions.

## Discussion

The overall clinical interpretation of the collected pain data indicates a meaningful therapeutic benefit for a substantial portion of the cohort. Across analyzable diaries, approximately 60-70% of participants showed improvement between baseline and post-treatment pain scores, with a mean reduction of about 3 points on a 0-10 numeric rating scale and many individuals achieving  $\geq 4$ -point decreases, a change generally regarded as a large and clinically important improvement. These findings are consistent with a study of the same device, in which 75% of chronic pain patients reported an average 49% reduction in pain and durable benefit at one year follow-up<sup>9</sup>. Our results also align with broader PBM literature, where low-level laser and LED-based therapies show moderate reductions in pain and inflammation across musculoskeletal conditions, including low back pain and knee osteoarthritis [10,11]. Collectively, these data support the use of combined low-level laser, LED, and electrical stimulation therapy as a non-pharmacologic option for chronic pain, particularly in the context of the ongoing need to reduce reliance on opioids and other systemic analgesics.

Detailed time-series analysis of hourly pain diaries adds novel insight into the temporal dynamics of pain during treatment. When averaged across all participants and days, pain intensity followed a reproducible diurnal pattern, with lowest scores in the early morning (06:00-10:00), rising to a midday peak around 11:00-17:00, followed by modest decline in the evening and further reduction overnight. This pattern of increased pain later in the active day partially mirrors experimental work demonstrating strong circadian modulation of pain sensitivity, with higher sensitivity in the late

evening and night and lower sensitivity in the afternoon [12]. Complementary scoping reviews in neuropathic and clinical pain conditions similarly report diurnal variation and highlight the potential for chronotherapy (i.e., timing treatments to circadian phase) to optimize analgesic benefit [13,14]. Our finding that many patients reached their lowest pain levels (often Level 1-2 sustained for up to 24 hours) on treatment days 7-14 suggests a cumulative therapeutic effect and raises the hypothesis that aligning device use with the individual's peak pain window (e.g., pre-midday) could further enhance outcomes. Future trials should prospectively manipulate treatment timing relative to circadian phase and daily activity to test this chronobiological optimization.

The distribution of responders and non-responders in this study also offers clinically relevant stratification signals. Robust responders (i.e., those achieving  $\geq 4$ -point improvement and prolonged low-pain intervals) were observed across multiple diagnostic groups, including degenerative disc disease, postsurgical pain, knee osteoarthritis, and mixed mechanical pain. Patients with structural pathology such as spine disease or joint replacement not only improved but also occasionally experienced high-intensity flare-ups (levels 8-10) early in the treatment course, especially on days 1-3, before stabilizing at lower pain levels. This transient exacerbation may reflect activity-related provocation, central sensitization being unmasked as baseline nociceptive load falls, or natural variability inherent to severe chronic pain [15,16]. By contrast, non-responders were over-represented among those with predominantly neuropathic or autoimmune etiologies (e.g., longstanding neuropathy, lupus), as well as among placebo, withdrawn, or lost-to-follow-up subjects. These diagnostic patterns echo prior PBM evidence, where effect sizes are largest for localized musculoskeletal pain and more modest or inconsistent for diffuse neuropathic syndromes<sup>10</sup>. Identifying phenotypes most likely to benefit (and those requiring multimodal combination strategies with pharmacologic or interventional approaches) will be critical for efficient, cost-effective deployment of this technology.

Sleep and cardiorespiratory measures provide an additional dimension to the clinical signal. Across ten treatment visits, most participants reported regular nocturnal sleep, and several demonstrated progressive increases in sleep duration over the treatment course. These observations align with prior work using the same device, where 74% of patients increased nightly sleep by an average of 51 minutes and 75% of those unable to sleep through the night at baseline reported full-night sleep at the end of treatment [9]. Our findings are also consistent with the larger body of evidence indicating a bidirectional relationship between chronic pain and sleep disturbance: insomnia and fragmented sleep predict incident and persistent musculoskeletal and neuropathic pain, and conversely, pain intensity worsens with short or poor-quality sleep. Mechanistically, disrupted sleep amplifies pain through altered dopaminergic and serotonergic signalling, activation of pro-inflammatory cytokines, and impaired endogenous pain modulation [16,17]. The

observation that many of our responders experienced both pain reduction and stable or improved sleep supports the premise that non-pharmacologic analgesic interventions capable of simultaneously lowering pain and improving sleep architecture may have disproportionately large functional benefits.

The placebo and withdrawal data further strengthen the interpretation that observed benefits are not solely attributable to nonspecific effects. Placebo-assigned participants rarely returned complete diaries and, when data were available, showed little or no sustained pain reduction, mirroring prior work in which placebo recipients using an inactivated device reported a net increase in pain and frequently dropped out. Similarly, subjects who withdrew due to unrelated medical events, environmental disruptions, or non-adherence could not be systematically evaluated, but their exclusion further biases the analyzable cohort toward conservative estimates of efficacy. Nonetheless, high rates of missing diaries (approximately 50% of the enrolled sample) and heterogeneity in diary quality emphasize the need for more robust adherence strategies, potentially including electronic diaries, automated reminders, and integration with wearable devices.

Several limitations should be acknowledged. First, the sample size within diagnostic subgroups was modest, limiting power to detect differential effects by condition and precluding formal multivariable modeling. Second, analgesic medications, physical therapy, and other co-interventions were not tightly standardized, so some of the observed improvements may partly reflect concurrent care rather than the device alone. Third, while the hourly pain ratings and sleep logs provide rich longitudinal data, they are self-reported and therefore subject to recall bias and expectancy effects. Fourth, although our findings are broadly consistent with other PBM and low-level laser trials [10,13,18], device parameters (wavelength, power, dose, electrode configuration) differ across systems and direct extrapolation to other technologies should be cautious. Finally, the study was not powered to examine long-term durability; given that prior work with the same platform has shown sustained benefit at one-year, future prospective follow-up of this cohort is warranted.

Despite these constraints, the present study adds important evidence that a combined low-level laser, LED, and electrical stimulation device can meaningfully reduce pain intensity, stabilize diurnal pain fluctuations, and improve sleep in a real-world chronic pain population with diverse etiologies. When viewed alongside mechanistic data that PBM enhances mitochondrial function, modulates inflammatory cytokines, and influences neurosensory pathways [19,20] and emerging work showing that circadian timing plays a major role in pain sensitivity [12,21], our findings support positioning this technology as part of a multimodal, circadian-informed, non-pharmacologic strategy for chronic pain management. Future high-quality randomized trials should stratify by pain phenotype, systematically assess sleep and functional outcomes, incorporate objective activity and circadian markers, and compare home-based

protocols against standard care. Such work will be essential to refine patient selection, optimize dosing and timing, and define the role of e-photonic therapy within comprehensive, opioid-sparing chronic pain programs.

## Conclusion

The findings of this prospective evaluation demonstrate that integrated multimodal biophysical therapy, combining photobiomodulation and electrical stimulation, can produce rapid and clinically meaningful improvements in individuals with chronic musculoskeletal, neuropathic, and mixed-etiology pain. Notably, most participants achieved substantial reductions in pain intensity, improved stability in diurnal pain patterns, and extended low-pain intervals within only a two-week treatment window, underscoring a therapeutic onset that is both swift and functionally relevant for real-world clinical practice. Improvements in sleep continuity and the absence of serious adverse events, further reinforce the safety and whole-system benefits of this approach. These outcomes, observed across diverse pain phenotypes and delivered through a single, non-pharmacologic device, support the clinical readiness of multimodal e-photonic therapy as a practical, scalable, and opioid-sparing option for patients who continue to experience persistent pain despite standard care. Given its low-risk profile, ease of administration, and potential to enhance functional outcomes, this therapy can be responsibly integrated into multidisciplinary pain management programs even as additional research progresses. At the same time, larger, well-controlled randomized trials remain essential to refine patient-selection criteria, quantify effect sizes across diagnostic subgroups, validate durability of benefit, and optimize treatment timing relative to circadian fluctuations in pain sensitivity. Such studies will help to define the full therapeutic potential and ideal implementation strategies for this technology. Nonetheless, the rapid and meaningful improvements documented in this cohort provide compelling early evidence that integrated multimodal biophysical therapy represents a valuable addition to contemporary chronic pain management and a promising path forward in efforts to reduce reliance on systemic analgesics, particularly opioids.

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