



## Photobiomodulation for Primary Dysmenorrhea: A Retrospective Observational Case Series in Three Women Using a Dual-Wavelength FEM Belt and Proposal for a Pilot Clinical Trial

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### Abstract:

### Objective:

We describe the PBM FEM belt, a photobiomodulation (PBM) device using 635-nm red and 880-nm near-infrared LEDs, along with preliminary clinical data for 3 cases regarding its application in the treatment of primary dysmenorrhea.

### Methods:

We conducted a retrospective observational case series involving three women who utilized the FEM belt. Standardized case report forms collected Visual Analog Scale (VAS 0–10) pain scores, duration of relief, medication usage, satisfaction levels, and the likelihood of recommending the device. All three available cases during the review period were included; no cases were excluded.

### Results:

The initial baseline VAS for all three women was 10. After one day of device usage, their VAS scores decreased by an average of 90% to a mean of 1. Two participants experienced immediate and rapid relief, and all three reported improvements on the initial day of use. Analgesic medication use was reduced or eliminated completely. In every case, satisfaction was 5 out of 5, and recommendation likelihood was rated 10 out of 10.

### Conclusions:

The PBM FEM belt provided quick, non-invasive and immediate dysmenorrhea relief and reduced analgesic usage in this small case series. The findings should be interpreted cautiously due to the small sample size and design of the case series. Controlled clinical studies are necessary.

**Keywords:** Photobiomodulation; primary dysmenorrhea; menstrual pain; non-pharmacological therapy; near-infrared therapy; LED therapy; menstrual cramps; low-level light therapy; red light therapy

### Abbreviations List

- **AI** – Artificial Intelligence
- **ATP** – Adenosine Triphosphate
- **CARE** – CAse REport Guidelines
- **COX-2** – Cyclooxygenase-2
- **EC** – Ethics Committee
- **EQ-5D** – EuroQol 5-Dimension Quality-of-Life Instrument
- **GCP** – Good Clinical Practice
- **IFU** – Instructions for Use
- **IRB** – Institutional Review Board
- **ISO** – International Organization for Standardization
- **LED** – Light-Emitting Diode
- **NIR** – Near-Infrared
- **NO** – Nitric Oxide
- **NSAID** – Non-Steroidal Anti-Inflammatory Drug
- **PBM** – Photobiomodulation
- **PGF2 $\alpha$**  – Prostaglandin F2-alpha
- **PGIC** – Patient Global Impression of Change

- **PROMIS** – Patient-Reported Outcomes Measurement Information System
- **ROS** – Reactive Oxygen Species
- **VAS** – Visual Analog Scale

### AI-Assistance Statement

*Artificial intelligence tools were used to support language refinement, organization, formatting, and preparation of parts of this manuscript. All scientific concepts, clinical interpretations, study design decisions, results, and conclusions are entirely the authors' original work. The authors reviewed, verified, and approved all content generated with AI assistance to ensure accuracy and integrity.*

### Introduction

Photobiomodulation (PBM) therapy utilizes low-intensity visible red ( $\approx 635$  nm) and near-infrared ( $\approx 880$  nm) light to activate cytochrome c oxidase within the mitochondrial respiratory chain, thereby enhancing ATP synthesis, augmenting microvascular circulation and reducing inflammation [1]. These effects help reduce inflammatory mediators involved in generating pain. Although NSAIDs and hormonal therapy are commonly used to treat menstrual pain, primary dysmenorrhea still affects 45–95% of women and results in substantial disability, missed work, and



economic burden [2–4]. This wide prevalence range reflects differences across populations and diagnostic criteria. Pain and discomfort typically commence 24–48 hours prior to menstruation and endure for as long as 72 hours.

Excessive production of prostaglandin F2 $\alpha$  (PGF2 $\alpha$ ) increases uterine tone, contractions, and ischemia, which results in cramping pain, nausea and impaired ability to function [3–5]. Common risk factors include younger age, not having children, heavy flow, and a family history [4,5]. The most common treatment is NSAIDs with hormonal contraceptives used for more severe cases [2–6]. Heat therapy, exercise, acupuncture, TENS, and nutritional supplements are common non-medicinal treatments [5–7].

This case series reviews the clinical utilization of a dual-wavelength PBM device (PBM FEM belt) for dysmenorrhea management and a suggested pilot controlled clinical trial.

#### Device Description

The PBM FEM belt (Figure 1) is a wellness device designed specifically for the female pelvic anatomy. It uses a dual-wavelength LED configuration: 33% red (635 nm) LEDs for superficial tissues and 66% near-infrared (880 nm) LEDs for deeper tissues ( $\approx$ 1–8 mm). The PBM FEM belt's average irradiance is 85.13 mW/cm $^2$  for the belt.



**Figure 1. PBM FEM belt with LED pad, battery, sleeve, and power cable.**

The PBM FEM belt includes: the ergonomic dual-wavelength LED treatment pad (635 nm and 880 nm), built-in battery module, control interface, and cable system.

The PBM FEM device is designed to work below 42°C, which ensures non-thermal operation and should not irritate the skin. By activating cytochrome c oxidase, the FEM belt boosts ATP production, facilitates nitric oxide release, and reduces

inflammatory mediators [1].

A 15-minute treatment session provides approximately 75 J/cm $^2$  of energy. The belt is designed to be worn against clean, bare skin for best results (Figure 2). It should not be used on areas with possible or current infection.



**Figure 2. Application of the PBM FEM belt over the lower abdomen.**

The PBM FEM belt is shown with the ergonomic dual-wavelength LED treatment pad over the lower abdominal region. During a 15-minute session, the device provides red and near-infrared light to

target the pelvic tissues that are related to primary dysmenorrhea.

**Table 1. FEM Wavelength Specifications and Applications**

Wavelength	Penetration Depth	Applications	Mechanism
635 nm 1/3	1-2 mm	Decrease inflammation; superficial tissue healing	Stimulate collagen; Activate fibroblasts, superficial anti-inflammation
880 nm 2/3	6-8 mm	Menstrual pain; deeper musculoskeletal tissues	Nitric oxide release; improved microcirculation, deeper ATP enhancement

**Methods****Study Design**

A retrospective observational case series was completed using structured, self-completed case report forms with no exclusions.

**Data Collection Procedures**

Standardized Visual Analog Scale (VAS 0-10) handouts were provided to participants before device use, with instructions to record their baseline pain at the onset of symptoms. Participants then repeated VAS scoring after completing the treatment period for that menstrual cycle. These written self-completed forms also captured medication use, duration of relief, satisfaction (1-5), and willingness to recommend the device (1-10). All VAS forms were collected at the end of the review period and entered into a secure electronic spreadsheet for analysis. This approach ensured uniform data capture and helped minimize recall bias in a retrospective series.

**Participants**

Inclusion criteria: women aged 18-40 years with clinically confirmed primary dysmenorrhea (no pelvic pathology via patient reported history), baseline VAS  $\geq 7$ , and no concurrent experimental therapy. All participants provided written informed consent.

This retrospective series included all three eligible women who met the inclusion criteria during the observation period. There were no cases which were removed, excluded, or selectively reviewed. Reporting all available cases reduces the risk of selection bias, which is particularly important in very small case

series.

**Intervention**

Participants used the PBM FEM belt intermittently for 15-minute sessions, 2 to 4 times daily, on painful days of the menstrual cycle (typically 4-6 days). The belt was placed directly to the lower abdomen. At  $75 \text{ J/cm}^2$  per 15-minute session, daily cumulative fluence dose was approximately  $150-300 \text{ J/cm}^2$ , depending on use frequency.

**Outcomes**

Primary outcome: Change in VAS pain score. Secondary outcomes: Change in pain levels, medication usage, satisfaction (1-5), and recommendation score (1-10). The data were summarized descriptively.

**Results**

All three women reported baseline VAS scores of 10, indicating severe menstrual pain. After one day of use of the FEM belt, average VAS decreased to 1 ( $\approx 90\%$  reduction). Mean post-treatment VAS was  $1.0 \pm 0.0$  (baseline  $10 \pm 0.0$ ). Two women experienced immediate relief; the third reported same-day improvement. All three reduced or discontinued analgesic medications. Satisfaction was uniformly 5/5, and recommendation scores were 10/10. Statistical analysis was not powered for inferential stats as the N was only 3.

There were no reported adverse effects from usage of the PBM FEM device.

**Table 2. Individual Case Data**

Case	Age	Baseline VAS	After VAS	Response/Pain	Medication usage	Satisfaction	Recommendation
YK	49	10	1	Immediate; lasted entire cycle	Reduced to none	5	10
H	45	10	1	Immediate; lasted entire cycle	Eliminated	5	10
SO	35	10	1	Same-day; lasted entire cycle	Reduced significantly	5	10

**Discussion**

PBM reduces dysmenorrhea symptoms via stimulation of mitochondria and enhancing microvascular perfusion. The 635/880-nm wavelengths activate cytochrome c oxidase, enhance ATP production, generate short-lived ROS signaling, and promote NO release. These effects align with the pathophysiology of primary dysmenorrhea, which involves elevated prostaglandins, COX-2 activation, ischemia, and uterine hypercontractility [1,3,7]. Non-pharmacological approaches such as heat therapy, acupuncture, and TENS have mixed evidence in dysmenorrhea, and their effectiveness often depends on how often they are used and how well the person tolerates them [5-7]. PBM differs from thermotherapy and neuromodulatory methods because its primary mechanism of action occurs at the mitochondrial level. This biochemical pathway may elucidate the swift onset of relief noted in our cases.

**PBM Comparison with Other Non-Pharmacological Options**

Heat therapy relies on surface heating to induce muscle relaxation, whereas TENS modulates nociception through peripheral nerve electrical stimulation. PBM, in contrast, acts primarily at the mitochondrial level. Red (635 nm) and near-infrared (880 nm) wavelengths stimulate cytochrome c oxidase, enhancing ATP production, nitric oxide release, and transient ROS signaling. These pathways produce downstream anti-inflammatory, vasodilatory, and analgesic effects that differ fundamentally from those achieved through external heat or neuromodulation [1,6,7]. This mitochondrial mechanism may explain the rapid relief observed in our cases, as PBM can directly modulate prostaglandin-driven dysmenorrhea pathways rather than treating symptoms indirectly.



All three participants experienced a swift and clinically meaningful reduction in their pain levels, potentially due to the modulatory effects of PBM. The cordless FEM belt makes treatment easy and convenient and allows the user to direct its placement and effect.

In all three cases, VAS pain decreased from 10 to 1 after one day of use. In two of the cases, pain relief was immediate, and in the third case, relief happened later on the same day. Everyone felt better throughout their entire menstrual cycle, and all decreased pain medication usage.

Multiple PBM studies have been shown to have pain-relieving and anti-inflammatory effects [1,6,7] and the reported patient data from this series aligns with the PBM pain-relief literature. Beyond gynecologic indications, PBM has been evaluated extensively for musculoskeletal pain. Randomized, placebo-controlled trials and meta-analyses in neck and other musculoskeletal disorders have shown that appropriately dosed low-level laser/PBM can produce clinically meaningful reductions in pain that persist for weeks to months after treatment. In a landmark meta-analysis of neck pain, PBM reduced pain by nearly 20 mm on a 100-mm VAS and benefits were maintained up to 22 weeks in chronic neck pain populations [10]. Likewise, a systematic review and meta-analysis of musculoskeletal disorders reported that PBM significantly reduced pain intensity in adults when World Association for Laser Therapy (WALT) dosing recommendations were followed [11]. Additional reviews in chronic pain populations support an analgesic signal across diverse conditions when PBM parameters are optimized[12]. These data suggest that the VAS reductions observed in our primary dysmenorrhea cases may be consistent with PBM's broader analgesic profile in pain management [10-12].

**Limitations:** Future studies must incorporate randomized, sham-controlled trials featuring objective pain evaluations and extended follow-up to mitigate issues related to small sample sizes, absence of controls, placebo effects, retrospective data, and potential reporting bias. Potential sources of bias include the authors' affiliation with the device manufacturer, retrospective data collection, and the absence of external assessment or monitoring. To reduce bias, standardized case report forms were utilized. All participants gave written consent for data usage, and no incentives or compensation were offered for participation. Additionally, because all three participants achieved near-identical outcomes, the risk of overestimation due to regression to the mean or expectancy effects cannot be fully excluded.

We propose a pilot multicenter randomized trial (N=100; 1:1 sham: active), assessing VAS reduction over three menstrual cycles, medication use, and quality-of-life metrics (PROMIS/EQ-5D, PGIC). The proposed trial would use change in VAS pain score during the first 48 hours of menstruation as the primary measure. Also assessed would be analgesic usage, PGIC, and quality-of-life measures (PROMIS/EQ-5D). The sample size of **N = 100 (50 active, 50 sham)** provides >80% power to detect a clinically meaningful **2-point difference in VAS pain reduction**, assuming a standard deviation of 2.5 and  $\alpha = 0.05$ .

The randomized trial will utilize a sham device identical in size, weight, appearance, LED layout, and user interface to maintain blinding. The sham device will include inactive LEDs that do not emit therapeutic wavelengths. Participant, investigator, and assessor blinding will be maintained.

Given the worldwide prevalence of primary dysmenorrhea— affecting an estimated 45–95% of menstruating women—and its status as a leading cause of adolescent school absenteeism and reduced workplace productivity, the cumulative economic burden is substantial at both individual and societal levels [2–

4]. Guidelines and population-based reviews emphasize not only the high use of NSAIDs and hormonal therapy but also the indirect costs associated with lost days of study and work, presenteeism, and impaired quality of life [2–4]. In this context, drug-free, self-managed options such as PBM devices may support women's health equity by improving access to effective pain relief without ongoing medication costs or frequent healthcare visits, particularly for individuals who cannot tolerate or prefer to avoid pharmacologic therapies.

### Conclusion

In this small, three-case series, the PBM FEM belt produced rapid and substantial non-pharmacological pain relief in all 3 women with primary dysmenorrhea. These findings are encouraging; however, they are only preliminary due to the very small sample size and absence of a control group. These observations are therefore considered hypothesis-generating. We note that a fully designed, adequately powered randomized controlled trial is required to determine the true effectiveness and generalizability of this PBM approach.

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