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In postnatal women with nipple pain, does photobiomodulation therapy (PBMT) at 660 nm compared with sham PBMT reduce pain on breastfeeding? A case series during COVID-19

Monique Ralph,[1] Cameron Hurst,[2] Sheridan Guyatt,[1] Kathleen Goldsmith,[3] E-Liisa Laakso[4]

[1]Physiotherapy Department, Mater Mothers' Hospitals South Brisbane, Queensland;
[2]Biostatistics, QIMR Berghofer Medical Research Institute Brisbane, Queensland;
[3]Parent Education and Support Services, Mater Health, South Brisbane, Queensland;
[4]Mater Research Institute-The University of Queensland, South Brisbane, Queensland, Australia

ABSTRACT

The analgesic role of PBMT for breastfeeding women with nipple pain is inconclusive. This study aimed to determine the efficacy of PBMT at 660 nm in postnatal women with nipple pain planning to exclusively breastfeed. A randomised, placebo-controlled clinical study was initiated at a tertiary hospital in Brisbane, Australia on the inpatient maternity wards from May 2020 to September 2020. Eligible participants were randomised into two groups, an intervention group receiving usual care and PBMT (Group A) and a control group receiving usual care and sham PBMT (Group B). Usual care involved consultation with a midwife and/or lactation consultant to assist with infant latching and breastfeeding positioning. PBMT (660 nm; 250 Hz; 17 mW; 0.5 cm^2 spot size) was administered three times within 24 hours. Nipple pain was the primary outcome measure analysed using a Visual Analogue Scale (VAS). Quality of life (QoL) and the participants' perceived efficacy of treatment were secondary outcome measures evaluated using the PROMIS Global Short Form and a combined 5-point Likert scale and thematic analysis, respectively. Due to the impact of COVID-19, only 10 participants were recruited. Compared to sham, three applications of PBMT at 660 nm provided no significant difference to participants' nipple pain, QoL or perceived efficacy of treatment. Three key themes of PBMT treatment were simplicity, safety and support. This study was unable to demonstrate the impact of PBMT at 660 nm on relieving nipple pain due to low participant numbers. An adequately powered RCT with COVID-19 modifications, is recommended.

Key words: photobiomodulation therapy; low-level laser therapy; laser, breastfeeding; nipple pain; nipple trauma.

Running Head:
Photobiomodulation therapy and nipple pain
Corresponding author:
E-Liisa Laakso, Mater Research Limited, Aubigny Place, Raymond Terrace, South Brisbane, Queensland, 4101 Australia.
Telephone: +61 7 31 636000; Fax: +61 7 31 631671
E-mail: liisa.laakso@mater.uq.edu.au

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Introduction

Breastfeeding has unequalled preventative health and wellness benefits to the mother and infant they feed[1] and is estimated to have an economic value in excess of $3 billion *per annum* in Australia alone.[2] Despite most women initiating breastfeeding, only 35% of infants in Australia are exclusively breastfed at the first six months of life.[3] Nipple pain is one of the leading causative factors of premature weaning with a prevalence rate of 27-53% of breastfeeding mothers.[4] The highest incidence of nipple pain occurs at day two and day three postnatally with risk factors including primiparity, ethnicity and inadequate handling between the mother and infant.[4]

Physiological manifestations of nipple pain can negatively influence maternal sleep, mood, and general activity.[5] If not managed, nipple trauma and pain can lead to the production of inflammatory cytokines and stress hormones which in turn can predispose the mother to a heightened risk of depression.[6] Early in-hospital management of nipple pain serves as a crucial factor to foster exclusive breastfeeding rates and nurture holistic maternal wellbeing.[7]

A 2014 Cochrane Database systematic review recognised that there is no clarity regarding the most effective treatment for nipple pain.[8] Based on a systematic review conducted by Niazi *et al.*, effective treatment options for nipple pain included the use of warm water compresses, menthol and breastfeeding correction yet these studies are dated.[9] Studies regarding other interventions are also limited and require further research to draw firm conclusions.[9] In the absence of a gold standard intervention for nipple pain, Photobiomodulation Therapy (PBMT) has received some attention in recent years as a potential treatment for nipple pain and trauma.

PBMT is the delivery of a specific wavelength of light, red and/or Near-Infrared (NIR), to a biological tissue to promote cellular restoration, reduce pain and minimise swelling.[10] Whilst red and NIR light both deliver non-thermal energy, red light targets more superficial tissue and is visible compared to NIR which purportedly penetrates deeper and is invisible to the human eye.[10] In addition to wavelength, there are multiple other parameters to consider when utilising PBMT including application time, time interval between treatments and frequency. The effectiveness of PBMT is dependent upon the treatment settings, which is complex considering optimal parameters remain unclear for many conditions[10] and past research methods vary significantly.[11-17] Disparate evidence suggests that PBMT using NIR wavelengths can reduce nipple pain,[11-13] and red wavelengths have reduced[14-16] or had no effect on nipple pain.[17]

Within the hospital inpatient model of PBM treatment, there are pragmatic levers for the intervention delivery and opportunity for repeated application in the immediate post-partum period. Previous studies utilising PBMT for nipple pain during in-hospital admissions have delivered treatments >24 hrs apart, which has led to significant drop-out rates for subsequent treatments due to participant discharge from hospital.[16] In the community setting, Buck *et al.* published a case study of a woman at three days post-natally with acute nipple pain.[15] The authors applied PBMT at three separate sessions over a 24-hour period, and demonstrated a significant reduction in pain and improved healing after this regimen of treatment.[15] If proven effective, such a regimen of treatment would be a suitable approach to utilise within a hospital setting, given the median baby-maternal length of stay (pre-COVID-19) in Australia is three days post-delivery.[18]

A leading cause of early breastfeeding cessation is nipple pain. PBMT offers a potential method to enhance breastfeeding uptake through tissue restoration and reducing pain. PBMT using red wavelengths is preferentially absorbed into superficial tissue compared to NIR and is under-investigated as a treatment for nipple pain and trauma. This study aims to investigate the effect of three sessions of PBMT at 660 nm within a 24-hour period during the mothers' early post-natal hospital admission. We also set out to understand the impact of PBMT on QoL in the participant groups, and to ascertain stakeholders' perception of effectiveness of PBMT for their symptomology.

Materials and Methods

This study was designed as a randomized, triple-blinded trial with sham control. Informed consent was obtained from all participants. All procedures were conducted at the Mater Mothers' Private Hospital in Brisbane, Australia and were approved by the Mater Misericordiae Limited Human Research Ethics Committee (HREC/MML/54337 (V3)). The study was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12619000981123) and commenced recruitment in May 2020.

Participants

Participants were recruited from new mothers by an independent physiotherapy research assistant with no prior knowledge of the patient. Eligible participants were randomly allocated to Group A (standard care+660 nm PBMT) or Group B (standard care+sham PBMT) through computed block randomization developed by an independent statistician. Randomisation of participants occurred after the consent process. Participants were screened prior to consent for inclusion if they were >18 years old with fluent English, had nipple pain after infant latching, delivered their baby through a participating obstetrics group practice, planned to exclusively breastfeed, and were to remain an inpatient for >24 hours with their infant rooming-in. Potential participants were excluded if they had breast malignancy, nipple tattoos, light photosensitivity, or any unmanaged psychological disorder.
Sample size was calculated for the primary pain outcome measure[19] and assumed a significance level of 0.05, 80% power, a moderately strong within-subject correlation (ρ=0.6), a within-standard deviation of 2.1 based on previous research findings[16] and a predicted dropout rate up to 15%. We calculated that 46 participants would be required to detect a 2-point difference in VAS pain scores.

PBMT specifications and application protocol

A MID-LITE 6565 active laser device (Irradia Australia) was utilized (Table 1). In the absence of a suitable sham for red light, an inoperable MID-LITE 904 laser device was used for the placebo. Both devices are similar in appearance, portable and have audible signals. All stakeholders were advised that the study was comparing red with NIR light.

Procedure

The participant, treating physiotherapists and assessor were blinded to group allocation. Blinding was achieved by a process of 'necessary deliberate deception' wherein participants and treating physiotherapists were led to believe that the study was comparing two wavelengths of PBMT, *i.e.*, red and NIR. All stakeholders were informed of the necessary deception at the end of the study. All participants received standard care consisting of midwife and/or lactation consultant assistance with breastfeeding positioning and infant latch correction occurring as necessary throughout the participants' hospital admission. No change was made to usual care procedures.
Hospital infection control procedures were followed and to ensure a standardised non-contact application a Medela 24 mm contact nipple shield (Medela Australia) was positioned over the participants' nipple and areola during the treatment for the diode to rest upon. The nipple shield was single patient use and washed and air dried between use. Diode output with the nipple shield *in situ*, was verified using a NOVA II laser power/energy meter (Ophir Australia) before commencement of the study, and at weekly intervals during

Table 1. Parameters of photobiomodulation therapy for nipple application.

Parameter	Red LASER	Sham NIR LASER
Diode type and number	GaAlInPh x 2	Not applicable
Wavelength	660 (± 10 nm)	Nil output
Pulse frequency	250 Hz	-
Average output power	17 mW each diode	-
Peak power	300 mW each diode	-
Spot size of each diode (cm^2)	0.5 cm^2	-
Irradiation time per site	39 s	-
Energy per site	1.33 J	-
Number of sites	3	-
Total irradiation time	132 s	-
Total dose applied to nipple	4 J	-
Beam shape	Divergent	-

the study.
Participants received three PBMT treatments in the first 24 hours after study enrolment. Time between treatments ranged from 7-17 hours. The affected nipple received three repeated applications at each treatment, and a single dose to three parts of the areolar (Figure 1) based on the dual diode design of the active MID-LITE 6565 PBMT device (Figure 2).

Outcome measures

The primary outcome measure was a Visual Analogue Scale (VAS) from 0 (no pain) to 10 (worst pain imaginable) of nipple pain whilst breastfeeding (after infant latching) before PBMT, and then after each subsequent PBMT application. The VAS is a reliable tool for the assessment of acute pain and is a commonly used measurement tool for evaluating nipple pain in breastfeeding women.[20,21]
Quality of life was measured with the PROMIS Global Short Form (GSF) questionnaire prior to the first and after the final PBMT application. The PROMIS GSF has been validated in the postnatal cohort for its two subscales being physical and mental health which have good internal consistency and reliability of α=0.75 and α=0.87, respectively.[22]
Participants' acceptability of PBMT was assessed after the last treatment by using a 5-point Likert scale, and an open comment for the participants' response. Open comments were analysed thematically.

Statistical analysis

All categorical variables using counts and percentages, and all continuous variables were described using means and standard deviations for variables likely to be normally distributed, and medians and inter-quartile ranges otherwise. As both the primary and one of the secondary outcome measures, VAS and QoL respectively, are continuous and were collected longitudinally, linear mixed modelling was used to examine the treatment effect, and how the treatment effect varied over time.
Participants' responses to the 5-point ordinal scale were analysed using the non-parametric Wilcoxon Sum of Ranks tests. Analysis was conducted using the R statistical package[23] with Linear Mixed modelling performed using the R library lme4.[24] A significance level of 0.05 was employed throughout all inferential analysis.
A thematic analysis was undertaken to analyse qualitative data using a widely recognised approach by Brawn & Clare.[25] This approach provides a robust stepwise method for identifying, analysing, and reporting themes within the data.[25] Data was independently reviewed by two members of the research team (MR+SG). Key themes were identified, and the research team together discussed these themes in relation to the data set and relevance to the research question.

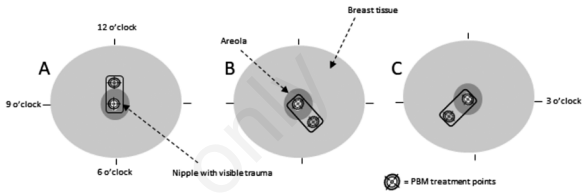

Figure 1. Photobiomodulation treatment configuration to nipple and surrounds.

Figure 2. Active photobiomodulation device (left) and sham photobiomodulation device (right).

Results

Power output of the active laser device remained stable throughout the study.

Participant characteristics

Due to the COVID-19 pandemic in 2020, a significant change to the length of hospital stay of new mothers occurred after recruitment commenced, and it became impossible to recruit the required participant numbers for successful completion of the study protocol. Recruitment was stopped in September 2020. Participant demographics and final number of participants in each group are shown in Table 2.

Pain visual analogue scale

Figure 3 shows the average pain (of left and right-side nipples) for each group over time. There was no significant difference between the two treatment groups on average (mean difference=1.09; 95%CI: −1.35,3.53; χ^2LRT=0.914; df=1; p=0.339); nor was there evidence to suggest a significant difference in overall pain at specific treatment times (χ^2LRT=2.120; df=3; p=0.548).

Quality of life

There is no evidence to suggest that 660nm PBMT improved overall QOL (Overall QOL mean difference =-0.007; 95%CI: −0.81,0.79; χ^2LRT=0.004; df=1; p=0.984); nor was there any evidence to suggest that the 660nm PBMT had a cumulative effect, nor a significant increase in the treatment effect over time (χ^2LRT=2.124; df=1; p=0.624).

There was no evidence to suggest a difference among the groups for the specific Physical and Mental QoL domains, either overall (Physical QOL mean diff=0.013; 95%CI: −0.09,0.92; χ^2LRT=0.002; df=1; p=0.963 (Figure 4); and Mental QOL mean diff=0.004; 95%CI: −1.1,1.08;

Table 2. Participant characteristics (SD=standard deviation; SC=skin colour; IQR=interquartile range).

Characteristic	Level	Overall (n=10)	Control (n=5)	Intervention (n=5)
Age (mean [SD])	-	32.80 (4.52)	33.00 (4.24)	32.6 (5.27)
Parity (%)	1 2	6 (60.0) 4 (40.0)	2 (40.0) 3 (60.0)	4 (80.0) 1 (20.0)
AreolaSC (median [IQR])		2.00 [2.00, 4.00]	2.00 [2.00, 3.00]	3.00 [2.50, 3.50]
Delivery mode (%)	Vaginal Caesarean section	4 (40.0) 6 (60.0)	2 (40.0) 3 (60.0)	2 (40.0) 3 (60.0)
Days.PostNatal (median [IQR])	-	2.00 [1.25, 3.00]	2.00 [1.00 3.00]	2.00 [2.00, 3.00]

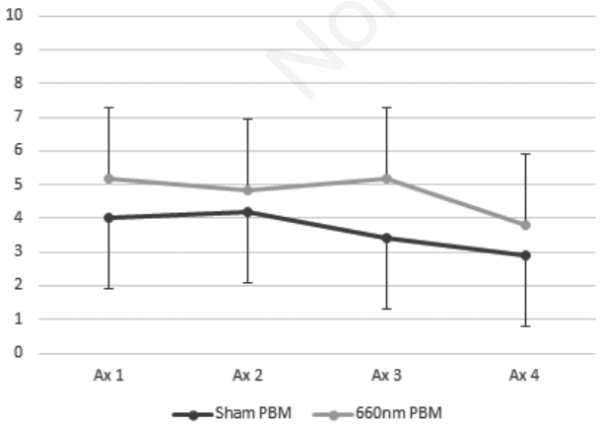

Figure 3. Average pain (combined left and right-side nipples) for each group over time (Ax=assessment).

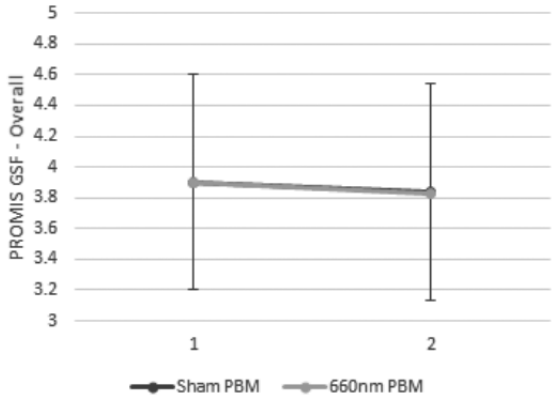

Figure 4. PROMIS Global Short Form (overall) quality of life score for each group (1=prior to treatment commencement; 2=after final treatment).

χ^2LRT=0.001; df=1; p=0.996, respectively) or in the Physical and Mental QOL profiles over time (χ^2LRT =0.210; df=1; p=0.647 and χ^2LRT =0.500; df=1; p=0.479, respectively).

Perceived effectiveness of PBMT

There was no difference in perceived effectiveness of treatment between groups (W=12, p=0.661, median difference=0). No-one who participated found PBMT unacceptable with seven of the nine participants agreeing it was acceptable, and two were undecided as they didn't experience any change in their nipple pain (both were in the sham group). All active group participants commented on signs of reduced symptoms after treatment exemplified by one participant stating, "I felt better after the third treatment so it definitely helps."

Thematic analysis

There were three key themes in the qualitative data being i) simplicity, ii) safety and iii) support. Participants described the simplicity of PBM treatments as quick, painless, uncomplicated, and easy to administer. An advantage of treatment identified by the participants is the positive safety profile of PBMT that it is low risk and non-invasive. Lastly, participants appreciated having a potential treatment to support their breastfeeding goals exemplified by a participant commenting PBMT has "low inconvenience to a new mother and helps achieve continued breastfeeding."

Discussion

The primary aim of this study was to investigate the effectiveness of PBMT at 660 nm compared to a sham control for nipple pain in post-natal women planning to exclusively breastfeed. The secondary aim was to compare PBMT at 660 nm to sham PBMT on its impact on QoL and to ascertain stakeholders' perceived efficacy of the therapy. Our study was significantly affected by the initial COVID-19 pandemic, and we were unable to recruit the planned numbers to the study. There is value in comparing our work with that of others to inform future research of the effect of red wavelengths of PBMT for nipple pain and/or trauma.

Whilst we were unable to determine if three applications of PBMT at 660 nm within 24 hours compared to sham influenced pain scores due to low participant numbers, we were able to show that the novel frequency of parameters previously utilised in a case study[15] was practical to utilise within an inpatient hospital setting evidenced by nil participant dropouts due to early discharge. A larger, adequately powered study would be required to demonstrate the effectiveness of the frequency utilised.

To our knowledge, ours is the first study to investigate the impact of QoL using the PROMIS GSF in women who have received PBM treatment for nipple pain and trauma. Post-partum QoL is important and can be impacted by infant feeding difficulties.[6] Although our findings were inconclusive, we believe that QoL should be evaluated in future studies. The PROMIS-GSF is translatable to a health utility value.

There was no difference in the participant perceived efficacy of treatment when comparing sham and control. Thematic analysis from nine out of ten participants revealed that PBMT had a positive safety profile and supported their breastfeeding goals. In our study, one participant reported an increase in nipple pain from 4/10 to 7/10 during the feed following the first application of PBMT, and she withdrew from the study. We adjusted our study protocol to record nipple and areolar skin tones and side effects for all other participants, although none occurred. Increased nipple pain was deemed to be a neural sensitivity response to PBMT, given the neuroanatomy of the nipple-areola complex and the role it has in breastfeeding[26] and has been reported in previous research.[17] However, given the disparate literature regarding nerve supply and sensitivity of the female breast, future studies of PBMT should consider the protocol and outcomes (including a plan of when to unblind and report side effects) based on participant skin tone/colour and how this may influence light absorption, response to treatment, and with consequences for guiding individualised PBMT doses.[27]

Placebo-controlled studies are considered the optimal way to investigate clinical interventions but much like acupuncture research, there is no effective inert sham for clinical studies of red light PBMT.[28] Theoretically, even small amounts of photonic energy delivered to biological tissues might influence those tissues depending on the state of the tissues and the amount of delivered energy. Given that the evidence regarding visible red-light wavelengths for nipple pain was nas-

cent,[9] we felt that further research investigating its effectiveness on nipple pain was required to understand the anecdotal and limited published research findings. We chose to do so by an ethically approved method of 'deliberate participant deception' to reduce the expectations that seeing light was important for an experimental or placebo effect. Hence, we led our participants and clinicians applying the treatment to believe the study was comparing red (visible) and NIR (invisible) PBMT. In fact, the NIR device was inoperable and served only as the sham intervention to mitigate the potential placebo effect of the visible red PBMT application.

Deliberate participant deception is appropriate in clinical research in only limited circumstances. In Australia, these circumstances are covered under the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research, Section 2.3.1 "Limited Disclosure".[29] In particular, the Statement permits the use of deception or limited disclosure where "there are no suitable alternatives involving fuller disclosure by which the aims of the research can be achieved", "the precise extent of the limited disclosure is defined" and "participants will not be exposed to an increased risk of harm as a result of the concealment or deception".[29] The authors were required to provide to participants at the end of the study "a full explanation, both of the real aims and/or methods of the research, and also of why the concealment or deception was necessary".[29] All research ethics requirements for deliberate participant deception were met for our study, and although we were unable to demonstrate whether the deception would have influenced the results, the recruited participants expressed no concerns once informed. We contend that the deception protocol is a method potentially suitable for blinding in other studies of visible wavelengths of light but the approach needs to be implemented carefully and under stringent ethical guidelines.

The main limitation of this study was that recruitment occurred during the peak Australian lock-down period of the 2020 COVID-19 pandemic, resulting in the recruitment pool of post-natal women being discharged earlier from hospital precluding the researchers' access to them. As a result, a decision was made by the investigators to cease recruitment and to report the work as a case series. We are undertaking further research in the study population in a community-based setting where factors related to COVID-19 can be mitigated.

Conclusions

This study was not able to demonstrate the effect of 660 nm PBMT compared to sham PBMT for nipple pain or QoL. Further adequately powered studies investigating the efficacy of PBMT impact on nipple pain are required to support anecdotal and limited research reports. This study provides guidance on designing a participant-, therapist- and assessor-blinded protocol in this field of women's health. This protocol is an ethically acceptable method for application for red PBMT with a suitable sham intervention to mitigate the potential placebo effect of visible light. The design if utilised in future research protocols will make trials of red light more robust.

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Conflict of interest: MR: no competing interests. Employed at Mater Health at the time of the research. Supported by a Mater Allied Health Services Research Seeding grant; SG: Employed at Mater Health at the time of the research. No other competing interests. CH: No competing interests. KG: Employed at Mater Health at the time of the research. No other competing interests; E-LL: Is a 1% shareholder in Symbyx Pty Ltd (Australia).

Ethics approval and consent to participate: the Mater Misericordiae Limited Human Research Ethics Committee approved the present study (HREC/MML/54337 (V3)). The study was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12619000981123).

Informed consent: all patients participating in this study signed a written informed consent form for participating in this study.

Patient consent for publication: the patients gave their written consent to use their personal data for the publication of this case report and any accompanying images.

Availability of data and materials: all data underlying the findings are fully available.

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