


Original Research

Photobiomodulation Therapy Plus Usual Care Is Better than Usual Care Alone for Plantar Fasciitis: A Randomized Controlled Trial

Ann K Ketz¹^a, Juanita Anders², Judy Orina³, Betty Garner⁴, Misty Hull³, Nicholas Koreerat⁵, Jeff Sorensen³, Candice Turner⁵, James Johnson⁶

¹ Recovery Sciences, Enosis, ² School of Medicine, Department of Anatomy, Physiology, and Genetics, Uniformed Services University of the Health Sciences, ³ The Geneva Foundation, ⁴ Betty K. Garner Sole Proprietorship, ⁵ Landstuhl Regional Medical Center, ⁶ Colorado State University

Keywords: photobiomodulation therapy, plantar fasciitis, tendinopathy, low level laser therapy, pain, function

<https://doi.org/10.26603/001c.90589>

International Journal of Sports Physical Therapy

Vol. 19, Issue 1, 2024

Background

Plantar fasciitis (PF) results in pain-related disability and excessive healthcare costs. Photobiomodulation therapy (PBMT) has shown promise for decreasing both pain and disability related to PF.

Purpose

The purpose was to assess the clinical impact of PBMT on pain and function in people with PF.

Study Design

Prospective, randomized controlled clinical trial

Methods

A convenience sample of adults with PF were randomly assigned to one of three groups: (1) usual care, (2) usual care plus nine doses of PBMT with 25W output power over three weeks, or (3) usual care plus nine doses of PBMT with 10W output power over three weeks. Both 10W and 25W PBMT participants received the same total dose (10J/cm²) by utilizing a simple area equation. Pain (with Defense and Veterans Pain Rating Scale) and function (by Foot and Ankle Ability Measure) were measured at baseline, weeks 3, and 6 for all groups, and at 13 and 26 weeks for PBMT groups.

Results

PBMT groups experienced a reduction in pain over the first three weeks (from an average of 4.5 to 2.8) after which their pain levels remained mostly constant, while the UC group experienced a smaller reduction in pain (from an average of 4 to 3.8). The effects on pain were not different between PBMT groups. PBMT in both treatment groups also improved function more than the UC group, again with the improvement occurring within the first three weeks.

Conclusions

Pain and function improved during the three weeks of PBMT plus UC and remained stable over the following three weeks. Improvements sustained through six months in the PBMT plus UC groups.

Level of Evidence

Level II- RCT or Prospective Comparative Study

^a Corresponding Author:
Dr. Ann K. Ketz, 5501 Lillehammer Lane, Apt 4305, Park City, UT 84098
Email: annketz@gmail.com
Phone: 435-901-5014

INTRODUCTION

Plantar fasciitis (PF) is the leading cause of heel pain in ambulatory settings, affecting up to 10% of adults.¹⁻³ Though the name is misleading, PF is not primarily an inflammatory condition.^{4,5} Repetitive trauma to the connective tissue causes acute inflammation. However, it is the combination of tissue destruction, fascial thickening, collagen necrosis, matrix calcification, peri-fascial edema, and alterations in vascularization that lead to the debilitating pain associated with PF.^{4,6-9}

Conservative PF treatment (e.g., reduced activity/loading, icing, stretching, orthotics, and taping/bracing) typically spans 6-12 months, and improvements are not often seen before six weeks of therapy.^{1,2,10} In some resistant cases, more aggressive, sometimes painful and invasive treatments are required, such as corticosteroid injections, radiation,¹¹ platelet-rich plasma injections,⁶ and surgery.^{1, 2,12}

Photobiomodulation (PBM) is an emerging therapy that uses non-ionizing, visible and near-infrared light to affect endogenous chromophores and elicit photochemical events at the cellular level.¹³ PBM therapy (PBMT) has been shown to improve other tendinopathies in studies of lateral epicondylitis, shoulder tendinopathy and Achilles tendinopathy when using optimized wavelengths and dosing parameters.¹⁴⁻¹⁶ The clinical benefit of PBMT for tendinopathies is thought to be mediated by collagen production,¹⁷ alignment of collagen fibers,¹⁸ and other mechanisms.¹⁹

Recent meta-analyses have reported positive findings supporting PBMT as an effective treatment modality for PF, though the conclusions are somewhat heterogeneous due to inconsistent dosing parameters (e.g., wavelength, power, application duration, intensity) and study methodologies.^{20,21} Specifically, the “dose” of PBMT is denoted by the intensity (J/cm^2) of the light delivered to the target area. However, the intensity is a product of the power (W) and application duration (sec); thus, equivalent “doses” could be achieved by proportionately increasing or decreasing both the power and application duration. Unfortunately, many studies do not adequately report these values, making direct comparisons difficult. As with any treatment, choosing the correct dose is essential to optimizing safety and efficacy.²² Of the multiple parameters for PBMT, wavelength and power are likely the most important, as wavelength determines the depth of photon penetration and power determines the number of photons delivered to the target tissue. PBM in the 810-980 nm wavelength range is known to penetrate the skin and superficial tissues to reach underlying tissues, such as muscle and tendon, including the target tissue of the plantar fascia.²³

PBMT is non-invasive and has potential to address the root cause/dysfunction of the injury, decrease the pain of PF quickly, and return individuals to increased function and physical activity. The goal of this study was to assess the clinical impact of PBMT on pain and function in people with PF.

MATERIALS AND METHODS

TRIAL DESIGN & PARTICIPANTS

This prospective, randomized controlled trial was conducted at a United States military medical center in Germany. Recruitment and enrollment of participants ($n = 114$) targeted adults between 18-65 years of age with symptoms of PF for at least three months (diagnosed by their primary healthcare providers, e.g., MD, DO, PA, NP), able to read and understand English language for consent purposes, and able to commit to six-week intervention and three and six month follow-up. Candidates were excluded for having a history of trauma, fracture, previous corticosteroid injections or other invasive treatment for PF to the symptomatic foot. Candidates with neuropathy or altered detection of skin temperature were excluded (including use of medication that may lead to the same), as well as those with greater than 15% of calf covered in tattoos, since pigment in ink absorbs light and can cause overheating of skin. Additionally, pregnant females and candidates with pacemakers were excluded.

The study protocol conforms to the Declaration of Helsinki and was approved by the Institutional Review Board of record (M-10548) and registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (registration number NCT03015116). Informed consent was obtained from all participants prior to enrollment in the study. Upon study enrollment, patients were allocated to study groups by the principal investigator, ensuring no healthcare provider bias. A parallel assignment study intervention model was employed. Due to the nature of the intervention, healthcare provider and patient blinding was not plausible, thus this study was conducted as open label.

INTERVENTIONS

USUAL CARE PROTOCOL

All participants were instructed to complete a usual care (UC) protocol daily for six weeks, beginning on day one, based on recommendations by current Clinical Practice Guidelines for PF treatment ([Figure 1](#)).²⁴⁻²⁶ The UC group participants were given the opportunity to receive PBMT outside of the study protocol for their affected foot after the completion of the 6-week study period.

PBMT PROTOCOL

Both intervention groups received PBMT three times a week for three weeks for a total of nine treatments and completed the UC protocol daily for six weeks, beginning on day one. All participants in both PBMT groups received the same dose at each treatment session. The only difference between groups was whether PBMT was delivered fast or slow. Here, “fast” PBMT refers to a dose of $10 J/cm^2$ delivered for one second per square centimeter of skin at 10W, while “slow” PBMT refers to the same dose of $10 J/cm^2$ but it was delivered for 0.4 seconds per square centimeter of skin at 25W.

Home Exercise Program Home Exercise Instructions			
Exercise	How do I do it?	How much and how often?	Picture
Calf Stretch- Knee Straight	While standing, with your involved foot furthest away from the wall, lean forward while keeping your heel on the floor and the back knee straight. Lean forward until you feel a stretch in the calf and/or Achilles region.	Perform this exercise 3 times daily for 2 repetitions holding each for 30 seconds.	
Calf Stretch- Knee Bent	While standing with your involved foot furthest away from the wall, lean forward, while keeping your heel on the floor and knee bent. Lean forward until you feel a stretch in the calf and/or Achilles region.	Perform this exercise 3 times daily for 2 repetitions holding each for 30 seconds.	
Self-stretching and Mobilization of Plantar Fascia and Flexor Hallucis Longus	Cross the affected leg over the nonaffected leg. While placing your fingers over the base of your toes, pull the toes back towards your shin until a stretch is felt in your plantar fascia. With your other hand, massage the plantar fascia and flexor hallucis longus from your heel towards your toes. Start gently at first then work deeper as tolerated.	Perform for 3 to 5 minutes.	
Single Leg Balance	Stand on the affected leg. Keep your balance as best you can without letting your other foot touch the floor. To make it more difficult, close your eyes and maintain your balance.	Perform this exercise 3 times daily for 2 repetitions holding each for 30 seconds.	
Toe Taps	While seated, raise your toes towards your knees while keeping your heel on the ground. Try to tap your toes as high and as fast as you can.	Perform this exercise 3 times daily for 1 minute.	
Calf Raises	While standing, slowly raise onto your toes, pause for 1-2 seconds, then slowly return your heel to the ground. For more of a challenge, perform on one leg while supporting your balance or while your toes are on a step.	Perform this exercise 3 times daily for 1 minute.	
Inversion/ Eversion Strengthening	While seated, with your affected leg try to make the biggest arch you can then do the opposite by making the smallest arch lifting the outside aspect of your foot off the ground as high as you can. Pause for 1-2 seconds at the top of each movement.	Perform this exercise 3 times daily for 1 minute.	

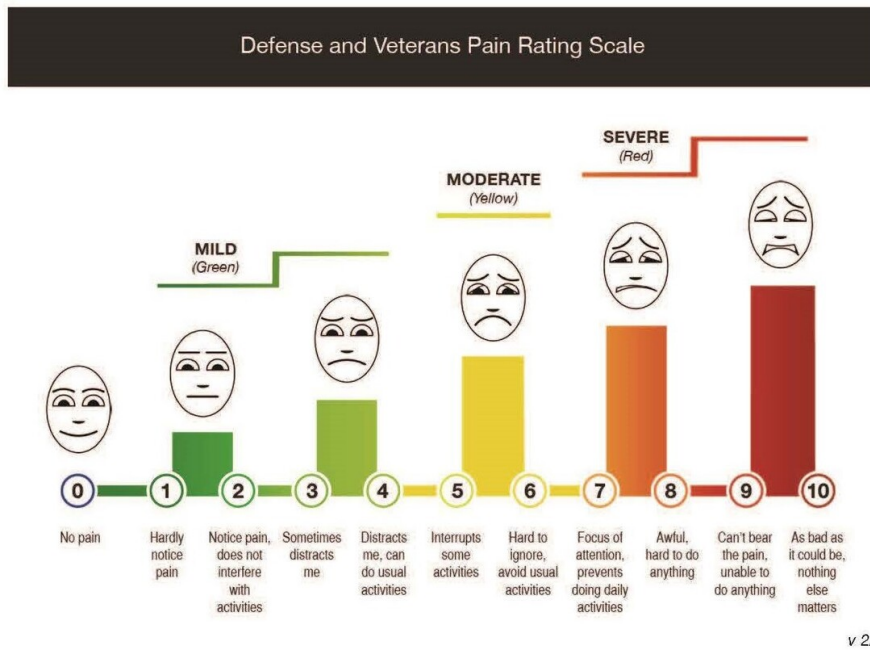
Figure 1. Usual Care Protocol

To achieve a standardized PBMT dose of 10 J/cm², the study team calculated the area of each participant's foot and calf at baseline and varied the time over which the total dose was delivered by calibrating to the output power (10W or 25W). Providers used a diode laser (LightForce EXPi, LiteCure/LightForce Medical, New Castle, DE, USA), with a blend of 20% 810nm and 80% 980 nm wavelength, continuous wave light delivered via a hand piece with an approximately 7 cm massage ball. Participants lay in a prone position, and the provider treated the plantar foot and dorsal calf surfaces in a serpentine movement, with the massage ball in perpendicular contact with the skin, slightly compressing underlying tissues. Treatment time was split

equally between the foot and the calf, with intermittent passive range of motion of the ankle.

OUTCOMES

The primary outcomes were pain, assessed by the Defense and Veterans Pain Rating Scale (DVPRS),²⁷⁻²⁹ and function, assessed by the Foot and Ankle Ability Measure (FAAM).³⁰ The 5-item DVPRS integrates a numeric pain rating scale with visual facial cues and word descriptors and four supplemental questions measuring pain interference (Figure 2).^{27,28} Permission is granted for clinicians and researchers to freely use the DVPRS as is, without alteration. All participants completed a daily DVPRS diary for six weeks, be-



DoD/VA PAIN SUPPLEMENTAL QUESTIONS

For clinicians to evaluate the biopsychosocial impact of pain

1. Circle the one number that describes how, during the past 24 hours, pain has interfered with your usual **ACTIVITY**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not interfere Completely interferes

2. Circle the one number that describes how, during the past 24 hours, pain has interfered with your **SLEEP**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not interfere Completely interferes

3. Circle the one number that describes how, during the past 24 hours, pain has affected your **MOOD**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not affect Completely affects

4. Circle the one number that describes how, during the past 24 hours, pain has contributed to your **STRESS**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not contribute Contributes a great deal

*Reference for pain interference: Cleveland CS, Fyian KM. Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singapore* 23(2): 129-138, 1994.

v 2.0

Figure 2. Defense and Veterans Pain Rating Scale tool

ginning on day one. In addition, four DVPRS supplemental outcomes were tracked: self-reported activity, mood, sleep interference, and stress.

The FAAM is a 29-item self-report instrument that assesses physical function in foot and ankle impairments. There are two subscales: activities of daily living (ADL) (21-item) and sports (8-item). The subscale items are scored on a 5-point Likert scale (4='no difficulty at all' to 0='unable to do') and then the points are converted to a percentage (100%=no dysfunction).³⁰ To measure the long-term outcomes in the PMBT groups, the study team sent a password-protected fillable PDF file of the DVPRS and FAAM to the PMBT participants via email so participants could report their pain and function at 13 and 26 weeks.

Participants also completed a daily medication and activity diary for descriptive analysis.

SAMPLE SIZE

Glaser Consulting performed power analysis using G*Power software.³¹ Considering the exploratory nature of the study and estimated population of participants, a small to medium effect size of 0.15 and autocorrelation of 0.3 was chosen, requiring n = 96 participants, or n = 32 participants per group. Participants were over-recruited by 20% (n = ~114, or n = 38 participants per group) to account for the potential attrition.

RANDOMIZATION

An Excel random number generator was used to assign participants to UC, UC plus 10W PBMT, or UC plus 25W PBMT, yielding 38 participants in each group.

STATISTICAL METHODS

Descriptive statics reported distributions of baseline demographics, daily activity and medication diary data. Inferential statistics used a nonlinear extension of generalized linear models, Hierarchical generalized additive models (GAM) using patient-level random effects with Gaussian distribution families. The hierarchical modeling with patient-level random effects handles the correlation of within-patient repeated measures, and the nonlinear GAM captures nonlinear effects.³² Where appropriate, hypothesis tests were two-sided and considered significant at the putative threshold ($\alpha=0.05$). Due to their nature, nonlinear effects are not interpreted in terms of coefficient p -values. Only linear effects have coefficient p -values that are readily interpretable. Nonlinear effects are interpreted graphically—that is, by inspecting partial dependence plots. These partial dependence plots are intuitive because they display the average patient-level effect in terms of its mean and confidence band. To assess whether effects are different between groups, simply look at their partial dependence plots; where the groups' confidence bands overlap, their effects are not statistically different; and where their confidence bands do not overlap, the effects are statistically different. In this way, partial dependence plots are intuitive and carry more information than coefficients and p -values from linear models. In other words, a modeling approach is used that is interpreted by looking at graphs, not p -values. Data normality and homoscedasticity were verified by Kolmogorov-Smirnov and Breusch-Pagan tests prior to analysis, respectively.

RESULTS

PARTICIPANT FLOW AND NUMBERS ANALYZED

By the end of the initial six weeks, seven, two and two participants had withdrawn from the UC, 10W, and 25W group respectively, leaving 31, 36, and 36 participants in each group with complete data for analysis of primary and secondary outcomes. UC group participation in the study ended after six weeks. For long-term follow-up, 88% of the PBMT groups were retained at three months and 76% by six months ([Figure 3](#)).

BASELINE DATA

Baseline demographic data showed representation among males (43.8%) versus females (56.3%); among Caucasian (58.8%) versus non-Caucasian (38.7%); and among military (47.4%) versus non-military (52.7%) (Supplemental File 1). The mean age of the participant population was 43.4 years old. While the study population showed a high percentage

of overweight and obese participants based on self-reported data, there was no significant difference between groups.

OUTCOMES AND ESTIMATION

PAIN

Because there was no difference in outcomes between the two treatment groups, for the primary analysis, the PBMT groups were pooled. Both PBMT groups received the same dose (10 J/cm²), with the only difference being the “speed” at which the total dose was delivered: either “slow” at one second per square centimeter, or “fast” at 0.4 seconds per square centimeter.

The pooled PBMT groups experienced a reduction in pain over the first three weeks, with a patient-level average change from 4.47 ± 0.13 to 2.84 ± 0.07 . The UC group experienced a small reduction in pain over the same period, having a patient-level average change from 4.03 ± 0.15 to 3.76 ± 0.08 . The effects on pain were not meaningfully different between PBMT groups, which were assessed graphically ([Figure 4](#)). Recall, the statistical significance of non-linear effects are interpreted not by coefficient estimates but by comparing confidence bands in partial dependence plots.

From three to six weeks, pain reduction appeared to plateau in the pooled PBMT groups (six-week mean 2.70, SE 0.1) and in the UC group (six-week mean 3.70, SE 0.15, $n=24$). When stratifying the 10W and 25W PBMT groups apart, no significant difference was observed, which is illustrated by their confidence bands ($2*SE$) overlapping in the partial dependence plot ([Figure 4](#)).

FUNCTION

Functional outcomes also showed some improvements in PBMT groups compared to UC ([Figure 5](#)). Patient-level average function per the FAAM sports subscale improved in the pooled PBMT groups from baseline (mean 0.45, SE 0.03, $n=73$) to six weeks (mean 0.66, SE 0.03, $n=70$), while functional improvement was slight, at best, in the UC group from baseline (mean 0.45, SE 0.04, $n=37$) to six weeks (mean 0.50, SE 0.04, $n=32$). There was no measured difference between the 10W and 25W PBMT groups in terms of FAAM sports.

Function, per the FAAM ADL subscale, did not seem to improve more in the pooled PBMT groups from baseline (mean 0.71, SE 0.02, $n=76$) to six weeks (mean 0.82, SE 0.01, $n=70$) than it improved in the UC group from baseline (mean 0.57, SE 0.02, $n=38$) to six weeks (mean 0.75, SE 0.03, $n=32$).

In contrast to the UC group, individuals in both PBMT groups reported notable (but non-significant) enhancements in the FAAM ADL subscale, surpassing validated thresholds for clinically meaningful changes at both 6-week and 6-month intervals. PBMT group participants met both the Minimal Detectable Change and Minimal Clinical Important Difference cutoff change scores of 6 and 8, respectively, when calculated at both six weeks and six months after treatment. These findings indicate that there is rea-

CONSORT

TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

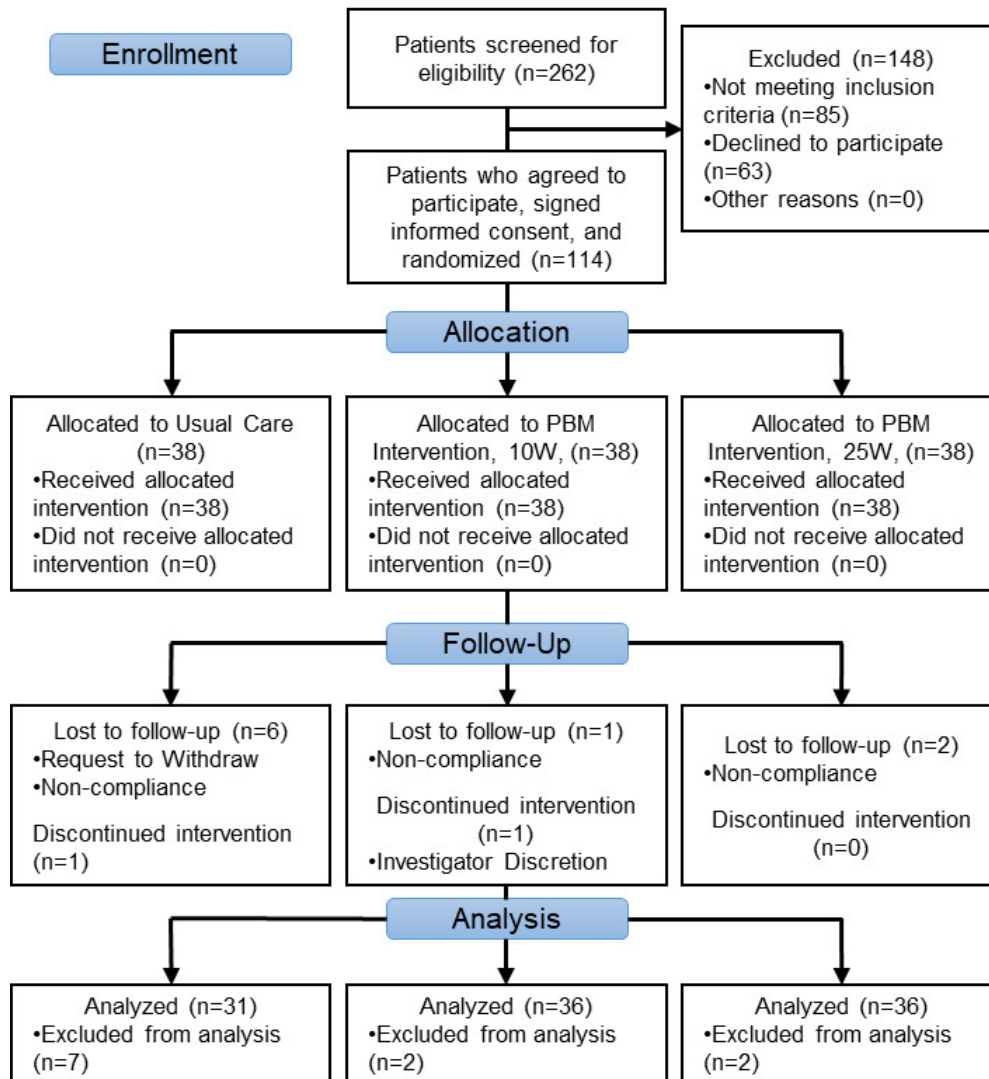


Figure 3. Recruitment and Retention Flow Diagram

sonable certainty of true change (95% CI) and that the change is clinically meaningful to the participants.³⁰

ANCILLARY ANALYSES

SUPPLEMENTAL DVPRS

The pooled PBMT groups demonstrated improved average patient-level changes to activity interference (from baseline 4.4 (SE 0.1) to six weeks 2.3 (SE 0.1)) compared to UC (from baseline 3.9 (SE 0.1) to six weeks 3.6 (SE 0.1)). Similar trends were observed for mood interference, sleep interference and stress contribution (Figure 6).

FITZPATRICK SKIN TYPE SUBGROUPS

Fitzpatrick Skin Type was significant in both the FAAM sports ($b = -.05$, $p = .03$) and FAAM ADL ($b = -.04$, $p = .002$) subscales, with the negative coefficient indicating a higher Skin Type score was associated with a lower FAAM score. Findings for pain outcomes were not significant between Fitzpatrick categories.

LONG-TERM FOLLOW-UP

Participants in both PBMT groups reported stable pain and function outcomes at 13 and 26 week follow-up time points. (Figures 7-9)

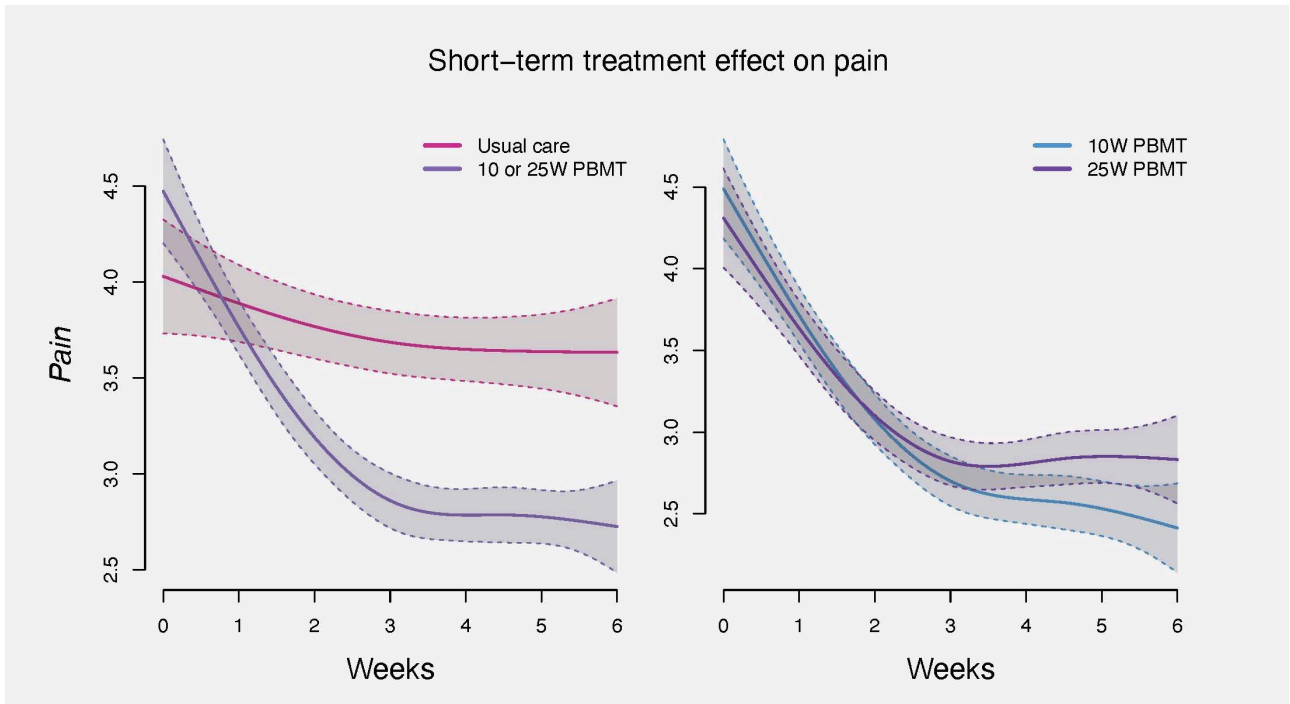


Figure 4. Short-term Defense and Veterans Pain Rating Scale Results

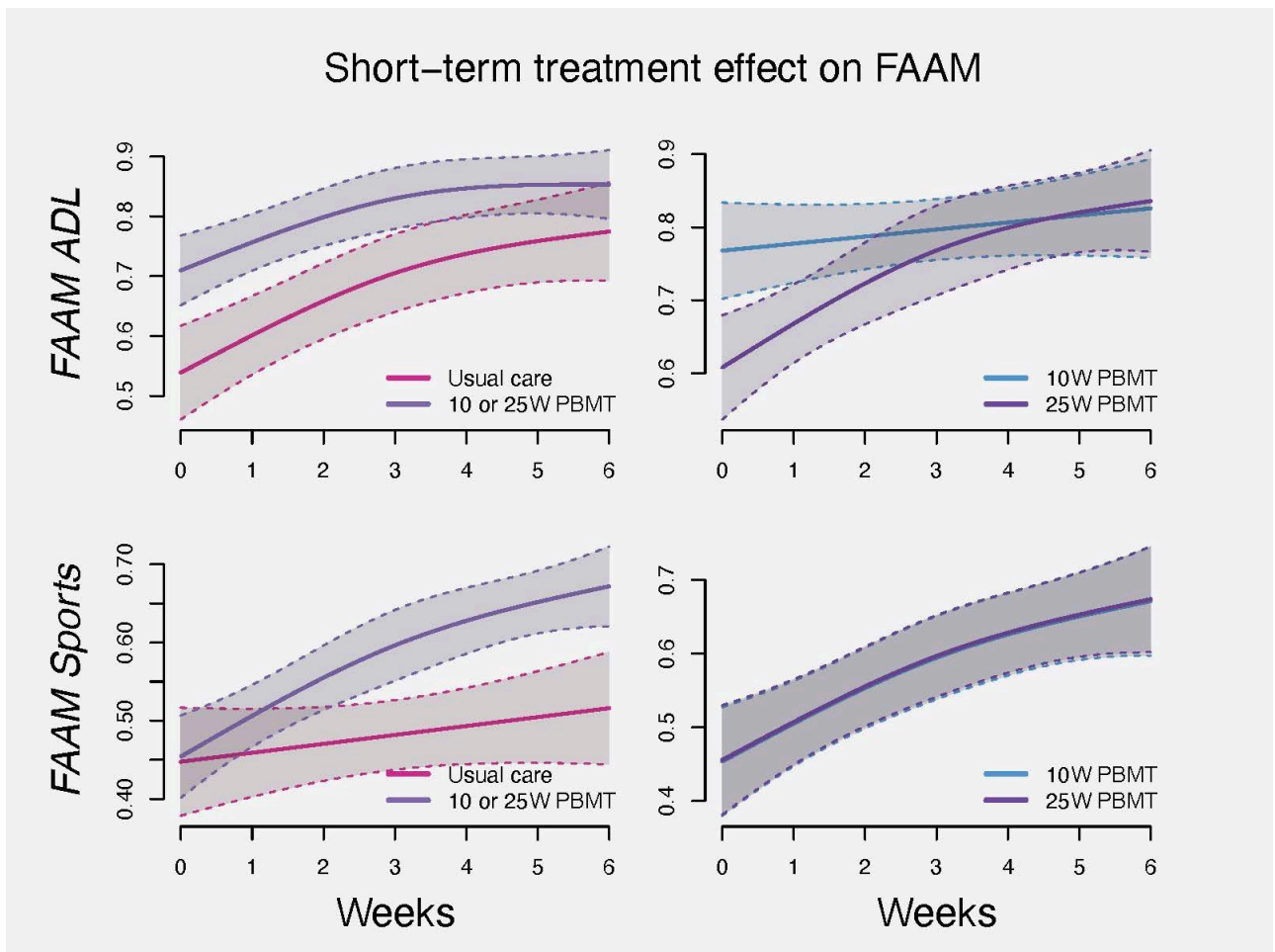


Figure 5. Short-term Foot and Ankle Ability Measure Results

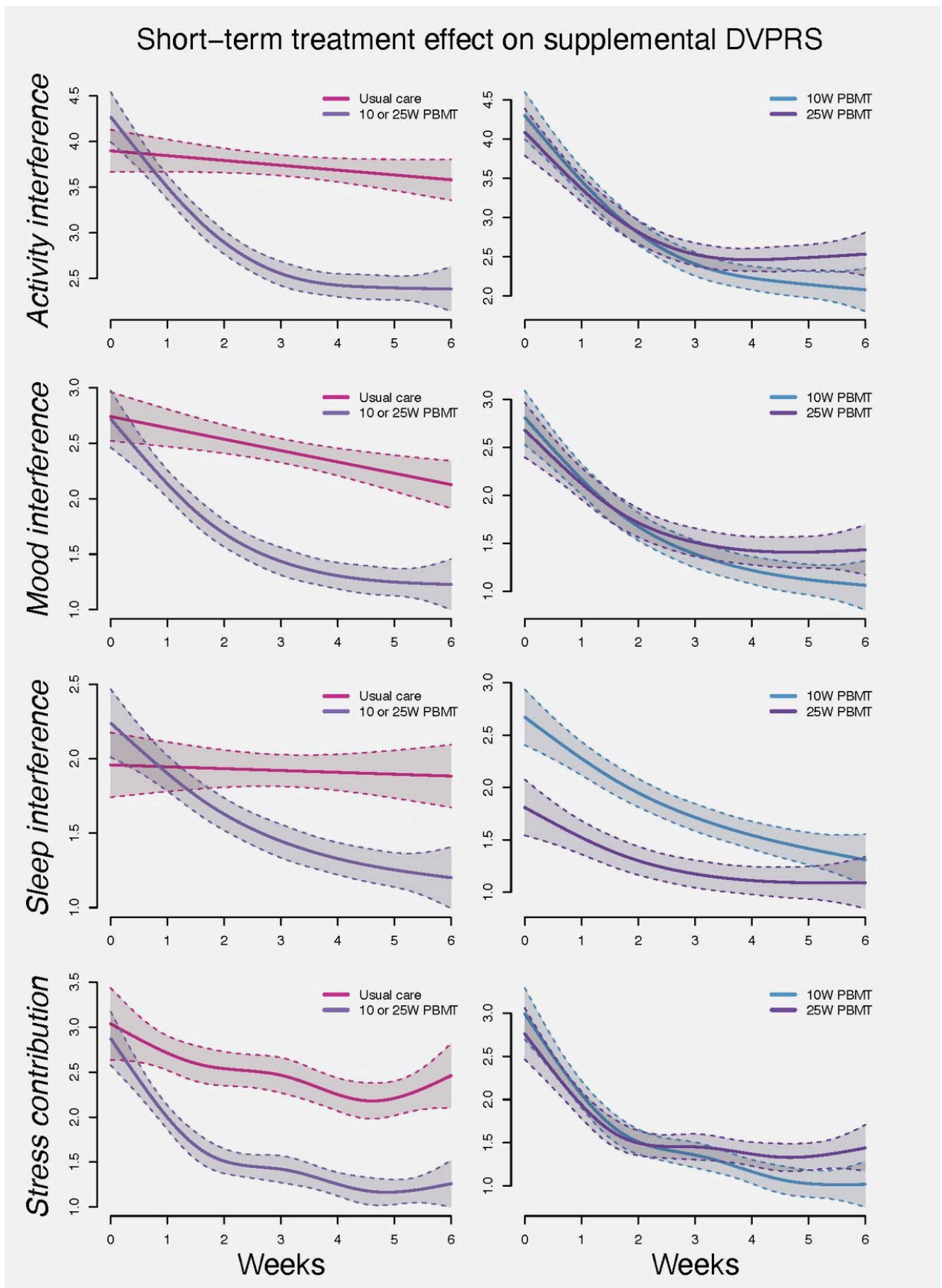


Figure 6. Short-term Defense and Veterans Pain Rating Scale Supplemental Results

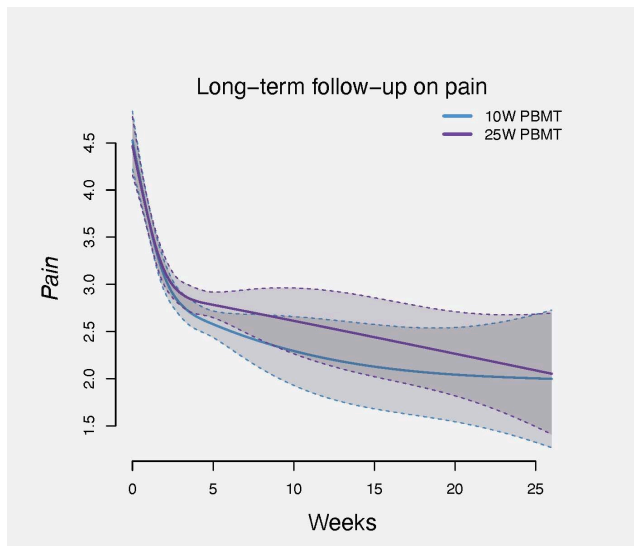


Figure 7. Long-term Defense and Veterans Pain Rating Scale Results

DISCUSSION

There were three main findings as relates to the study's primary aims: 1) PBM therapy at both power levels (i.e., 10W and 25W; both administered to achieve 10J/cm² dose) resulted in clinically relevant significant reductions in pain, whereas the UC group did not exhibit reductions in pain, 2) PBM therapy at both power levels resulted in some increases in the FAAM Sports subscale; however, this did not achieve the level of statistical significance and no differences were noted in FAAM ADL between both PBM groups and the UC group, 3) no statistically significant differences were noted in pain, FAAM Sports, or FAAM ADL between the 10W and 25W PBM groups.

Two recent systematic reviews and meta-analyses reported significant improvements in pain (Visual Analog Scale) and function (Foot Function Index) in favor of PBMT over control.^{22,33} Other PMBT studies for PF, including those in recent meta-analyses, used different outcome measures, wavelengths, and other parameters, and often did not report their methods completely making direct comparison challenging.^{20,21,34-38} However, the findings are consistent in that pain and function are improved over time when the appropriate wavelength and other treatment parameters are chosen (i.e., power, application time).

Participants in this study reported a mean baseline pain level between 4.1-4.3, and the UC group reported this consistent level of pain through the end of the protocol. In contrast, participants in both PBM groups reported clinically relevant and significant decreases in pain throughout the 6-week protocol period. Additionally, both PBM group participants reported a two-point decrease in the pain scale by long-term follow-up. While long-term data were not collected for the UC group, their consistent pain scores through the study period stand in stark contrast to the decreases noted in the PBM groups. Salaffi and colleagues analyzed clinically meaningful change in numeric pain rat-

ing scale scores in chronic musculoskeletal injuries and reported that patients considered their pain to be "much better" when their scores decreased by 2 points.³⁹ This cutoff was reached in both PBMT groups at their long-term follow-up demonstrating clinical improvements in pain and long-term relief of PF symptoms. While it was not a direct aim of this study, medication diary descriptive statistics indicated that daily non-steroidal anti-inflammatory drug consumption decreased in the treatment groups but remained steady or increased in UC participants. This is an interesting finding that warrants further study considering the risks of long-term non-steroidal anti-inflammatory drug use.

While this study did not explore the underlying biological mechanisms for decreased pain in the PBM groups, other works have investigated the impact of PBM on various tendinopathies and may inform the results seen herein. It is well known that effective treatments for PF and other tendinopathies must address the underlying injury mechanism versus the symptoms only. Chronic PF (and other tendinopathies) results in a recurring cycle of degeneration.⁴ Animal studies using PBMT in other tendinopathy models support that correctly dosed PBMT penetrates to the fascia and results in beneficial changes to the degenerated tissue. These changes include synthesis, organization, and strengthening of damaged collagen fibers, activation of matrix metalloproteinases, cellular proliferation and new blood supply growth.^{19,40-42} In clinical trials, investigators have reported significant decreases in plantar fascial thickness, indicating restructuring of damaged fascia.^{35,38} Taken together, these findings provide support to explain the self-reported improvement in functional outcomes in this and other studies, and future studies should include these objective measures of structural change.

Selection of wavelength and other treatment parameters is essential for effective treatment. The vast majority of PBMT studies in PF select wavelengths in the near-infrared range. At lower wavelengths (500nm to 800nm), melanin in the skin is the primary chromophore, limiting penetration to deeper structures, however light in the 800nm to 1000nm range is ideal for reaching the injured tissue in PF.^{23,45}

Because study patients were treated over both the plantar surface of the foot, which typically has less melanin than other skin, as well as the dorsal calf and ankle, the impact of Fitzpatrick skin type on outcomes was evaluated. The study had a significant finding that higher Fitzpatrick category was predictive for poorer outcomes in the FAAM ADL and sports subscale, but had no significant impact on pain. Though these results should be interpreted cautiously due to the small number of participants in higher Fitzpatrick categories, it is important to remember when designing treatment protocols to consider using a longer wavelength option (e.g., 980 nm) for those individuals.

IMPLICATIONS

With advances in technology making devices with higher power outputs available, understanding appropriate use of PBMT parameters is more essential than ever before. The current study utilized a simple area equation to ensure all

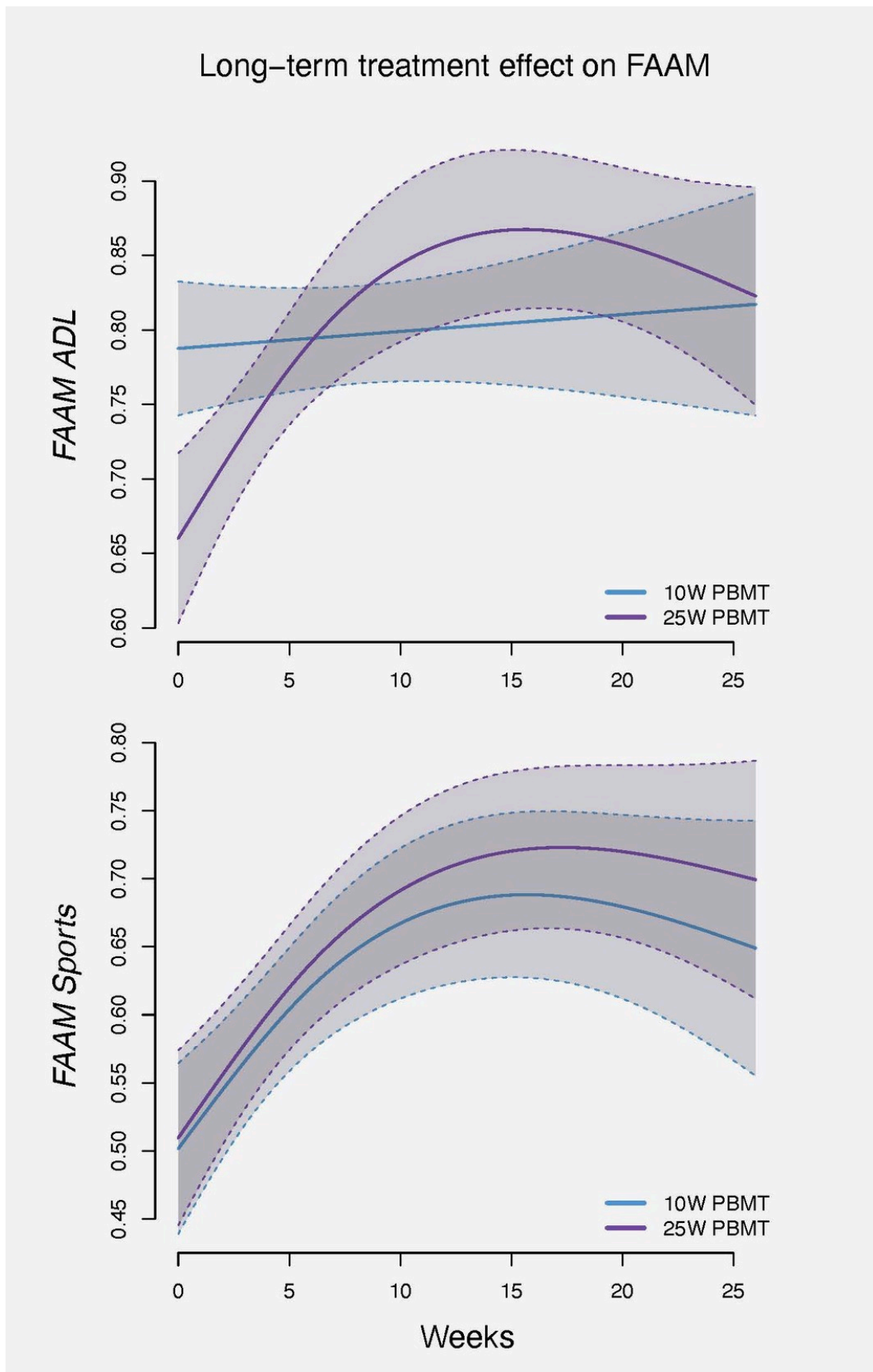


Figure 8. Long-term Foot and Ankle Ability Measure Results

Long-term follow-up on supplemental DVPRS

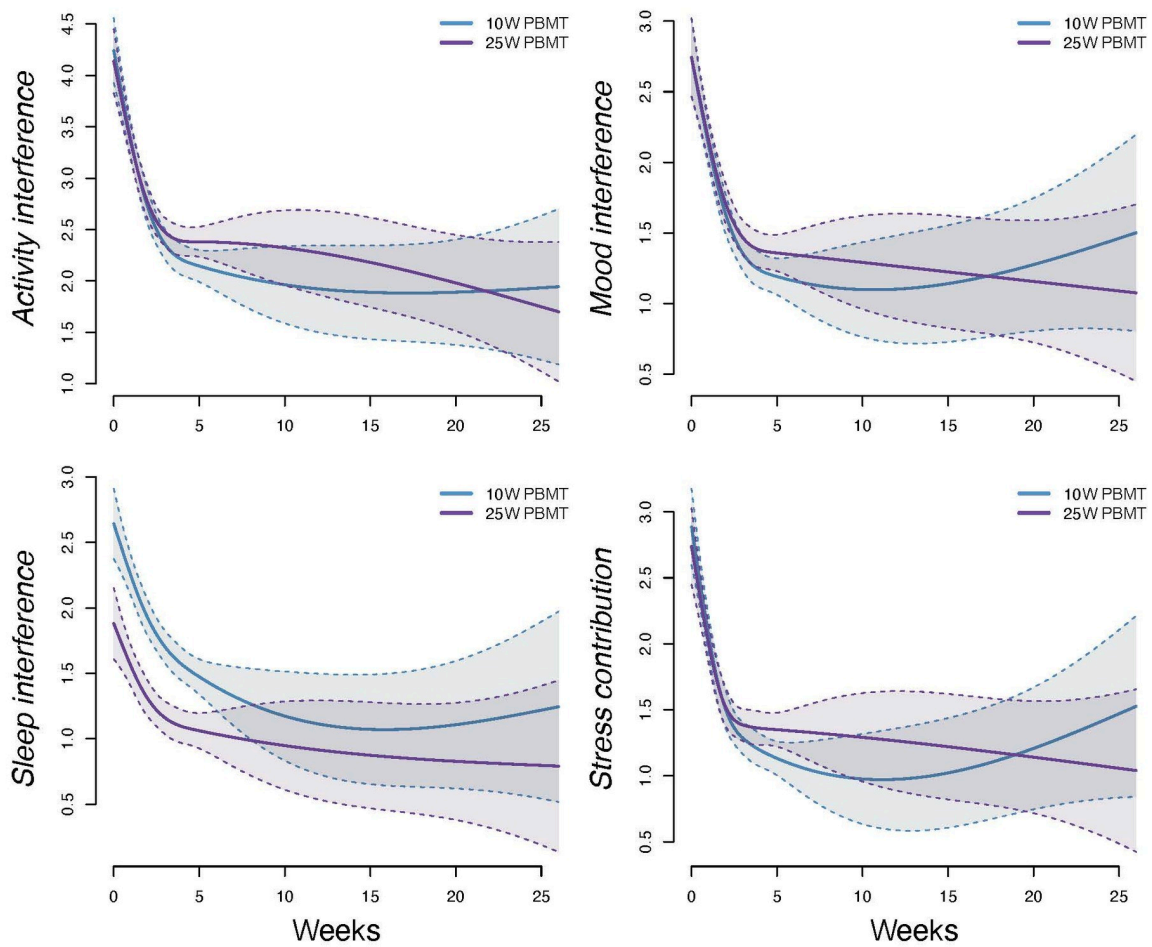


Figure 9. Long-term Defense and Veterans Pain Rating Scale Supplemental Results

participants received a standardized energy density of 10 J/cm², regardless of power output. Participants in the both the 10W and 25W groups tolerated the treatment well with no adverse outcomes related to the treatment and reported similar improvements in pain and function. The primary difference between the treatment groups was in the time required to complete the treatment – given the same surface area treated, using 25W is 2.5 times quicker than 10W. In a clinical setting, this equates to being able to treat more patients safely and effectively, while reserving the option to decrease the power output at their discretion without jeopardizing patient outcomes.

LIMITATIONS

The positive outcomes of this study are limited by the absence of a sham treatment group; however, at the time of the study, an indistinguishable sham control option was not available.⁴⁴ Secondly, the lack of long-term follow-up in the UC group does limit the utility of the long-term data from both PBM groups. Finally, though conducted in a military treatment facility setting, the demographic distribution of participants are consistent with similar trials,²² and

therefore, supports this treatment protocol for future studies and clinical treatment. Future studies should investigate the impact of even higher-powered lasers (e.g., 40W) to ensure the lack of difference between power groups reported herein persists with even higher laser powers.

CONCLUSION

The standardized PBMT protocol plus UC resulted in statistically and clinically significant decreased pain and improvements in function in the FAAM sports subscale compared to usual care alone. Additionally, there was no difference in outcomes between the groups receiving 10W and 25W output power with a standardized energy density of 10 J/cm² over the long-term, with improvements being sustained at the 6-month follow-up point. The lack of adverse events and significantly and clinically meaningful decreases in pain scores support previous work that PBMT is a safe, innovative treatment targeting the root cause of injury to the PF.

ACKNOWLEDGEMENTS

TriService Nursing Research Program (N16-P09) provided the funding to conduct this study, and the device was provided via a Cooperative Research and Development Agreement between LiteCure, LLC and the Clinical Investigation Regulatory Office, U.S. Army Medical Research and Materiel Command.

Ann Ketz, RN, PhD is currently employed by Enovis, DJO Global (now Enovis), who acquired LiteCure, LLC; she was not employed by them for the duration of the study. Juanita Anders, BA, MS, PhD, has received Cooperative Research and Development Agreement (CRADA) between USUHS and Lite Cure, LLC; received equipment from B&W Tek, Irradia, Lite Cure, Nitto Denko, PhotoThera; serves on advisory board for Lite Cure, LLC. The remaining authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article.

The study was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (registration number NCT03015116) and was carried out in accordance with ICH/GCP guidelines.

DISCLAIMER

The information, content, and conclusions in this paper do not represent the official position or policy of, nor should any official endorsement be inferred by, the TriService Nursing Research Program, Uniformed Services University of the Health Sciences, Landstuhl Regional Medical Center, the Department of Defense, or the U.S. Government.

Submitted: January 05, 2023 CST, Accepted: October 30, 2023 CST

© The Author(s)



This is an open-access article distributed under the terms of the Creative Commons Attribution 4.0 International License (CCBY-NC-4.0). View this license's legal deed at <https://creativecommons.org/licenses/by-nc/4.0> and legal code at <https://creativecommons.org/licenses/by-nc/4.0/legalcode> for more information.

REFERENCES

1. Dyck DD Jr, Boyajian-O'Neill LA. Plantar fasciitis. *Clin J Sport Med*. 2004;14(5):305-309. doi:10.1097/00042752-200409000-00010
2. Rosenbaum AJ, DiPreta JA, Misener D. Plantar heel pain. *Med Clin North Am*. 2014;98(2):339-352. doi:10.1016/j.mcna.2013.10.009
3. Scher DL, Belmont PJ Jr, Bear R, Mountcastle SB, Orr JD, Owens BD. The incidence of plantar fasciitis in the United States military. *J Bone Joint Surg Am*. 2009;91(12):2867-2872. doi:10.2106/jbjs.i.00257
4. Lemont H, Ammirati KM, Usen N. Plantar fasciitis: a degenerative process (fasciosis) without inflammation. *J Am Podiatr Med Assoc*. 2003;93(3):234-237. doi:10.7547/87507315-93-3-234
5. Orchard J. Plantar fasciitis. *BMJ*. 2012;345:e6603. doi:10.1136/bmj.e6603
6. Franceschi F, Papalia R, Franceschetti E, Paciotti M, Maffulli N, Denaro V. Platelet-rich plasma injections for chronic plantar fasciopathy: a systematic review. *Br Med Bull*. 2014;112(1):83-95. doi:10.1093/bmb/ldu025
7. Hammer WI. The effect of mechanical load on degenerated soft tissue. *J Bodyw Mov Ther*. 2008;12(3):246-256. doi:10.1016/j.jbmt.2008.03.007
8. Miller LE, Latt DL. Chronic plantar fasciitis is mediated by local hemodynamics: Implications for emerging therapies. *N Am J Med Sci*. 2015;7(1):1-5. doi:10.4103/1947-2714.150080
9. Tountas AA, Fornasier VL. Operative treatment of subcalcaneal pain. *Clin Orthop Relat Res*. 1996;(332):170-178. doi:10.1097/00003086-199611000-00023
10. Schwartz EN, Su J. Plantar fasciitis: a concise review. *Perm J*. 2014;18(1):e105-107. doi:10.7812/tpj/13-113
11. Canyilmaz E, Canyilmaz F, Aynaci O, et al. Prospective randomized comparison of the effectiveness of radiation therapy and local steroid injection for the treatment of plantar fasciitis. *Int J Radiat Oncol Biol Phys*. 2015;92(3):659-666. doi:10.1016/j.ijrobp.2015.02.009
12. Rompe JD. Plantar fasciopathy. *Sports Med Arthrosc Rev*. 2009;17(2):100-104. doi:10.1097/jsa.0b013e3181a3d60e
13. Anders JJ, Lanzafame RJ, Arany PR. Low-level light/laser therapy versus photobiomodulation therapy. *Photomed Laser Surg*. 2015;33(4):183-184. doi:10.1089/pho.2015.9848
14. Haslerud S, Magnussen LH, Joensen J, Lopes-Martins RA, Bjordal JM. The efficacy of low-level laser therapy for shoulder tendinopathy: a systematic review and meta-analysis of randomized controlled trials. *Physiother Res Int*. 2015;20(2):108-125. doi:10.1002/pri.1606
15. Tumilty S, Munn J, Abbott JH, McDonough S, Hurley DA, Baxter GD. Laser therapy in the treatment of achilles tendinopathy: a pilot study. *Photomed Laser Surg*. 2008;26(1):25-30. doi:10.1089/pho.2007.2126
16. Tumilty S, Munn J, McDonough S, Hurley DA, Basford JR, Baxter GD. Low level laser treatment of tendinopathy: a systematic review with meta-analysis. *Photomed Laser Surg*. 2010;28(1):3-16. doi:10.1089/pho.2008.2470
17. Hashmi JT, Huang YY, Osmani BZ, Sharma SK, Naeser MA, Hamblin MR. Role of low-level laser therapy in neurorehabilitation. *PM R*. 2010;2(12 Suppl 2):S292-305. doi:10.1016/j.pmrj.2010.10.013
18. Oliveira FS, Pinfildi CE, Parizoto NA, et al. Effect of low level laser therapy (830 nm) with different therapy regimes on the process of tissue repair in partial lesion calcaneus tendon. *Lasers Surg Med*. 2009;41(4):271-276. doi:10.1002/lsm.20760
19. Ng GY, Chung PY. Effects of a therapeutic laser and passive stretching program for treating tendon overuse. *Photomed Laser Surg*. 2012;30(3):155-159. doi:10.1089/pho.2011.3095
20. dos Santos SA, Sampaio LM, Caires JR, et al. Parameters and Effects of Photobiomodulation in Plantar Fasciitis: A Meta-Analysis and Systematic Review. *Photobiomodul Photomed Laser Surg*. 2019;37(6):327-335. doi:10.1089/photob.2018.4588
21. Wang W, Jiang W, Tang C, Zhang X, Xiang J. Clinical efficacy of low-level laser therapy in plantar fasciitis: A systematic review and meta-analysis. *Medicine*. 2019;98(3):e14088. doi:10.1097/md.00000000000014088

22. Lopes-Martins RAB, Marcos RL, Leal-Junior ECP, Bjordal JM. Low-level laser therapy and World Association for Laser Therapy dosage recommendations in musculoskeletal disorders and injuries. *Photomed Laser Surg.* 2018;36(9):457-459. doi:10.1089/pho.2018.4493
23. DeTaboda L. What Wavelengths of Light are the Best for Photobiomodulation (PBM)? Published 2019. Accessed July 22, 2019. <https://www.litecure.com/about-photobiomodulation/wavelength-selection/>
24. Martin RL, Davenport TE, Reischl SF, et al. Heel pain-plantar fasciitis: revision 2014. *J Orthop Sports Phys Ther.* 2014;44(11):A1-A33. doi:10.2519/jospt.2014.0303
25. McPoil TG, Martin RL, Cornwall MW, Wukich DK, Irrgang JJ, Godges JJ. Heel pain--plantar fasciitis: clinical practice guidelines linked to the international classification of function, disability, and health from the orthopaedic section of the American Physical Therapy Association. *J Orthop Sports Phys Ther.* 2008;38(4):A1-A18. doi:10.2519/jospt.2008.0302
26. Thomas JL, Christensen JC, Kravitz SR, et al. The diagnosis and treatment of heel pain: a clinical practice guideline-revision 2010. *J Foot Ankle Surg.* 2010;49(3 Suppl):S1-S19. doi:10.1053/j.jfas.2010.01.01
27. Buckenmaier CC III, Galloway KT, Polomano RC, McDuffie M, Kwon N, Gallagher RM. Preliminary validation of the Defense and Veterans Pain Rating Scale (DVPRS) in a military population. *Pain Med.* 2013;14(1):110-123. doi:10.1111/j.1526-4637.2012.01516.x
28. Nassif TH, Hull A, Holliday SB, Sullivan P, Sandbrink F. Concurrent validity of the Defense and Veterans Pain Rating Scale in VA outpatients. *Pain Med.* 2015;16(11):2152-2161. doi:10.1111/pme.12866
29. Polomano RC, Galloway KT, Kent ML, et al. Psychometric testing of the Defense and Veterans Pain Rating Scale (DVPRS): A new pain scale for military population. *Pain Med.* 2016;17(8):1505-1519. doi:10.1093/pm/pnw105
30. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Van Swearingen JM. Evidence of validity for the Foot and Ankle Ability Measure (FAAM). *Foot Ankle Int.* 2005;26(11):968-983. doi:10.1177/10711007050260113
31. Mascha EJ, Vetter TR. Significance, errors, power, and sample size: The blocking and tackling of statistics. *Anesth Analg.* 2018;126(2):691-698. doi:10.1213/ane.0000000000002741
32. Liu S, Rovine MJ, Molenaar PC. Selecting a linear mixed model for longitudinal data: repeated measures analysis of variance, covariance pattern model, and growth curve approaches. *Psychol Methods.* 2012;17(1):15-30. doi:10.1037/a0026971
33. Wang W, Jiang W, Tang C, Zhang X, Xiang J. Clinical efficacy of low-level laser therapy in plantar fasciitis: A systematic review and meta-analysis. *Medicine.* 2019;98(3):e14088. doi:10.1097/md.00000000000014088
34. Cinar E, Saxena S, Uygur F. Low-level laser therapy in the management of plantar fasciitis: a randomized controlled trial. *Lasers Med Sci.* 2018;33(5):949-958. doi:10.1007/s10103-017-2423-3
35. Kiritsi O, Tsitas K, Malliaropoulos N, Mikroulis G. Ultrasonographic evaluation of plantar fasciitis after low-level laser therapy: results of a double-blind, randomized, placebo-controlled trial. *Lasers Med Sci.* 2010;25(2):275-281. doi:10.1007/s10103-009-0737-5
36. Ordahan B, Karahan AY, Kaydok E. The effect of high-intensity versus low-level laser therapy in the management of plantar fasciitis: a randomized clinical trial. *Lasers Med Sci.* 2018;33(6):1363-1369. doi:10.1007/s10103-018-2497-6
37. Takla MKN, Rezk SSRA. Clinical effectiveness of multi-wavelength photobiomodulation therapy as an adjunct to extracorporeal shock wave therapy in the management of plantar fasciitis: a randomized controlled trial. *Lasers Med Sci.* 2019;34(3):583-593. doi:10.1007/s10103-018-2632-4
38. Ulusoy A, Cerrahoglu L, Orguc S. Magnetic resonance imaging and clinical outcomes of laser therapy, ultrasound therapy, and extracorporeal shock wave therapy for treatment of plantar fasciitis: A randomized controlled trial. *J Foot Ankle Surg.* 2017;56(4):762-767. doi:10.1053/j.jfas.2017.02.013
39. Salaffi F, Stancati A, Silvestri CA, Ciapetti A, Grassi W. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *Eur J Pain.* 2004;8(4):283-291. doi:10.1016/j.ejpain.2003.09.004
40. Alves AN, Fernandes KPS, Deana AM, Bussadori SK, Mesquita-Ferrari RA. Effects of low-level laser therapy on skeletal muscle repair: a systematic review. *Am J Phys Med Rehabil.* 2014;93(12):1073-1085. doi:10.1097/phm.0000000000000158
41. Casalechi HL, Leal-Junior ECP, Xavier M, et al. Low-level laser therapy in experimental model of collagenase-induced tendinitis in rats: effects in acute and chronic inflammatory phases. *Lasers Med Sci.* 2013;28(3):989-995. doi:10.1007/s10103-012-1189-x

42. Guerra F da R, Vieira CP, Almeida MS, Oliveira LP, de Aro AA, Pimentel ER. LLLT improves tendon healing through increase of MMP activity and collagen synthesis. *Lasers Med Sci*. 2013;28(5):1281-1288. [doi:10.1007/s10103-012-1236-7](https://doi.org/10.1007/s10103-012-1236-7)

43. Hale GM, Query MR. Optical constants of water in the 200-nm to 200-microm wavelength region. *Appl Opt*. 1973;12(3):555-563. [doi:10.1364/ao.12.000555](https://doi.org/10.1364/ao.12.000555)

44. Prasad V, Cifu AS. The necessity of sham controls. *Am J Med*. 2019;132(2):e29-e30. [doi:10.1016/j.amjmed.2018.07.030](https://doi.org/10.1016/j.amjmed.2018.07.030)

SUPPLEMENTARY MATERIALS

Supplemental File 1

Download: <https://ijspt.scholasticahq.com/article/90589-photobiomodulation-therapy-plus-usual-care-is-better-than-usual-care-alone-for-plantar-fasciitis-a-randomized-controlled-trial/attachment/187894.docx>
