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RESEARCH ARTICLE

Photo-biomodulation Therapy Combined with Specific Wavelength LED Arrays for Accelerating Tendon Healing: A Randomized Controlled Trial

Dr. Nilank Dwivedi, Department of Orthopaedics, Katihar Medical College and Hospital, Katihar, Bihar,
nilankd123@gmail.com

Abstract

Chronic issues and protracted recovery periods might result from tendon damage. One novel non-invasive treatment that may aid in tissue healing is photo-biomodulation therapy (PBMT) using LED lights. Using specific LED wavelengths, the study aimed to investigate whether PBMT could aid in the healing of severe tendon injuries and improve patient function. 65 individuals participated in a double-blind, randomised controlled experiment at Katihar Medical College in India in 2023. Both the intervention and control groups of patients were formed. In addition to receiving standard care, the control group received sham therapy, while the treatment group received PBMT. Throughout the course of eight weeks, outcomes were evaluated for pain reduction, functional improvement, and ultrasonic healing. According to the objectives, the treatment group outperformed the control group in terms of functional improvements and pain scores. Additionally, ultrasound studies showed reduced inflammation and better tendon structure in PBMT-treated individuals. All things considered, PBMT greatly promotes tendon repair, lessens discomfort, and boosts function when paired with normal treatment.

Keywords: Tissue repair, low-level laser treatment, tendon healing, LED therapy, and photo-biomodulation

INTRODUCTION

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Millions of people worldwide are affected by tendon injuries, which pose serious challenges for clinical treatment due to their inadequate vascularization and slow healing ability (Sharma & Maffulli, 2005). Because tendons have a limited blood supply, recovery times are lengthy, frequently lasting months, and may involve complications like adhesion development, decreased range of motion, and chronic pain (Kannus, 2000).

Rest, physical therapy, and anti-inflammatory medicines are the main components of conventional tendon injury treatment methods. However, these traditional methods sometimes produce less-than-ideal results, particularly in terms of functional recovery and healing time (Khan et al., 2002). As a result, adjunctive treatments that might improve the body's innate healing mechanisms have become increasingly popular.

Previously known as low-level laser therapy (LLLT), photo-biomodulation therapy (PBMT) has become a potential non-invasive treatment option for a variety of musculoskeletal disorders (Chung et al., 2012). By using low-power light at certain wavelengths, PBMT stimulates cellular processes, improves mitochondrial function, and facilitates tissue healing (Hamblin, 2017). The therapeutic mechanism is mostly explained by chromophores in the mitochondrial respiratory chain absorbing photons, which causes more adenosine triphosphate (ATP) to be produced and improves cellular metabolism (Karu, 1999).

Compared to conventional laser systems, light-emitting diode (LED) technology's recent improvements have made PBMT more affordable and readily available. LED arrays are especially well-suited for treating tendon injuries because they can provide therapeutic light with a uniform power density across a bigger treatment area (Whelan et al., 2001). Because of its ideal tissue penetration and cellular absorption properties, the dual-wavelength method, which mixes red (660nm) and near-infrared (850nm) light, has demonstrated outstanding outcomes (Lim et al., 2015).

PBMT has been shown in previous studies to have potential benefits for tendon healing, such as increased collagen production, greater tensile strength, and a lower inflammatory response (Oliveira et al., 2009; Marcos et al., 2012). However, the majority of the research has been done on animal models, and few well-designed clinical trials assess the efficacy of LED-based PBMT in treating human tendon injuries.

The main target of this experiment was to conclude how well photo-biomodulation therapy using certain wavelength LEDs works to speed up tendon recovery and enhance functional outcomes in individuals with recent tendon injuries. Secondary goals included evaluating pain alleviation, range of motion improvement, and ultrasonographic healing symptoms.

MATERIALS AND METHODS

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2.1 Study Design and Setting

Between January 2023 and December 2023, the Department of Orthopaedics at Katihar Medical College & Hospital in Katihar, Bihar, India, carried out a double-blind, randomized controlled experiment for this investigation. The Institutional Ethics Committee gave the study protocol its approval (Ethics Approval No: KMCH/IEC/2022/ORG/125).

2.2 Participants

Inclusion Criteria:

• People between the ages of 18 and 65

• Tendon injuries occurring within seven days of the incident

• Ultrasonography revealed a verified tendon injury

• Informed written consent

• Capacity to schedule routine follow-up appointments

Exclusion Criteria:

• Full tendon rupture needing surgical treatment

• A prior tendon injury at the same location

• Lactation or pregnancy

• Systemic inflammatory disorders or malignancy

• The use of photosensitizing drugs at the moment

• Issues with the skin around the treatment region

• Inability to adhere to treatment protocol

2.3 Blinding and Randomization

Using computer-generated randomization in blocks of four, eligible applicants were arbitrarily assigned to either the treatment group (PBMT + standard care) or the control group (sham therapy + standard care). The allocation was kept hidden by using sealed, opaque envelopes. The assignment of groups was kept secret from the outcome assessors and the participants. Due to the intervention's nature, the treating physiotherapist was not blind, but they were told not to share the treatment assignment with participants or assessors.

2.4 Interventions

Treatment Group: Participants underwent photobiomodulation therapy with a dual-wavelength LED array system (MedLite Pro-2000, India) that simultaneously delivered red (660 nm) and near-infrared (850 nm) light. The parameters of treatment were as follows:

• 40 mW/cm2 is the power density.

• Energy density: 4 J/cm²

• Duration of therapy: 100 seconds each site

• Therapy area: six spots surrounding the afflicted tendon

• Frequency: For the first four weeks, there will be five sessions each week; for the next four weeks, there will be three sessions per week.

• The entire course of therapy lasted eight weeks.

Participants in the control group underwent fake therapy using the same equipment but with the LED

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arrays turned off. The treatment was administered in the same position and for the same amount of time.

Regular Treatment: Both groups underwent the same physiotherapy regimen, which included:

• The first week or two of the treatment focuses on rest and protection.

• Light range of motion exercises (weeks 3–4)

• Progressive strengthening activities (week 5-8)

• Home exercise program and patient education

2.5 Measures of Outcome

Main Results:

1. Pain Assessment: The Visual Analogue range (VAS) uses a range of 0 (no pain) to 10 (the most excruciating pain) to assess discomfort.

2. Functional Assessment: The Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire (Hudak et al., 1996)

3. Ultrasonographic Parameters: Tendon thickness, echogenicity, and vascularity measured by high-resolution ultrasonography (GE LOGIQ P9, 12 MHz linear probe)

Secondary Results:

1. Range of motion (goniometric measurements)

2. Revisit the activity timeline

3. Ratings for patient satisfaction

4. Negative occurrences

2.6 Evaluation Timetable

Outcome assessments were performed at several points during the treatment: at the beginning (T0), and then at two weeks (T1), four weeks (T2), six weeks (T3), and eight weeks (T4). At 12 weeks, a last follow-up (T5) was done to ascertain the long-term results.

2.7 Statistical Analysis

A two-point distinctness on the VAS scale is deliberate and solid, in accordance with previous studies. A minimum of 25 communities were needed for each group's sample height, likely a 5% importance level, 80% power, and a predictable difference of 2.5. In order to give a reason for a 20% nonconformist rate, 65 sign-ups were inducted. Data study was conducted utilizing SPSS form 26.0. Continuous variables were elucidated as mean predictable difference, and explicit variables were presented by percentages and frequencies. Groups were distinguished utilizing free t-tests, unending and explicit variables were distinguished utilizing chi-square tests, and material vacillations were analysed utilizing ANOVA, accompanying a meaning level of $p < 0.05$.

RESULTS

3.1 Features of the Participants

There were 65 participants in the study; 32 were in the control group and 33 were in the therapy group. Following the withdrawal of three participants—two from the treatment group and one from the control

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group—62 people finished the trial. The two groups initially shared similar characteristics.

Table no.1: Study Participants' Preliminary Features

Characteristic	Treatment Group (n=31)	Control Group (n=31)	p-value
Age (years)	38.4 ± 12.7	40.2 ± 14.1	0.612
Gender (Male/Female)	18/13	17/14	0.826
BMI (kg/m²)	24.8 ± 3.2	25.1 ± 3.6	0.738
Injury site			0.542
- Achilles tendon	12 (38.7%)	10 (32.3%)	
- Patellar tendon	8 (25.8%)	9 (29.0%)	
- Rotator cuff	6 (19.4%)	8 (25.8%)	
- Other	5 (16.1%)	4 (12.9%)	
Time since injury (days)	3.2 ± 1.8	3.6 ± 2.1	0.421
Baseline VAS score	7.8 ± 1.4	7.6 ± 1.6	0.615
Baseline DASH score	68.4 ± 12.3	66.9 ± 13.7	0.648

3.2 Primary Outcomes

Pain Reduction (VAS Scores): Sizable contrasts in pain reduction were perceived between groups throughout the study period. The treatment group showed more rapid and sustained pain reduction compared to controls (Table 2).

Table no.2: Pain Scores on the Visual Analogue Scale (VAS) With Time

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Time Point	Treatment Group	Control Group	Mean Difference (95% CI)	p-value
Baseline	7.8 ± 1.4	7.6 ± 1.6	0.2 (-0.6 to 1.0)	0.615
2 weeks	5.2 ± 1.8	6.8 ± 1.9	-1.6 (-2.6 to -0.6)	0.003
4 weeks	3.1 ± 1.5	5.4 ± 2.1	-2.3 (-3.3 to -1.3)	<0.001
6 weeks	1.8 ± 1.2	4.2 ± 1.8	-2.4 (-3.2 to -1.6)	<0.001
8 weeks	1.2 ± 0.8	3.4 ± 1.2	-2.2 (-2.8 to -1.6)	<0.001
12 weeks	0.8 ± 0.7	2.1 ± 1.4	-1.3 (-1.9 to -0.7)	<0.001

Functional Outcomes (DASH Scores): The treatment group demonstrated significantly better functional outcomes throughout the study period, with sustained improvements at 12-week follow-up (Table 3).

Table no.3: DASH Functional Scores Over Time

Time Point	Treatment Group	Control Group	Mean Difference (95% CI)	p-value
Baseline	68.4 ± 12.3	66.9 ± 13.7	1.5 (-5.4 to 8.4)	0.648
2 weeks	52.7 ± 15.2	58.3 ± 16.8	-5.6 (-14.1 to 2.9)	0.194
4 weeks	35.8 ± 12.4	48.2 ± 14.7	-12.4 (-19.7 to -5.1)	0.001
6 weeks	23.1 ± 10.8	39.5 ± 13.2	-16.4 (-22.8 to -10.0)	<0.001
8 weeks	15.3 ± 8.2	32.7 ± 12.1	-17.4 (-22.8 to -12.0)	<0.001
12 weeks	12.4 ± 7.9	25.8 ± 11.3	-13.4 (-18.4 to -8.4)	<0.001

3.3 Ultrasonographic Assessment

Ultrasonographic evaluation revealed significant improvements in tendon healing parameters in the treatment group (Table 4). Enhanced tendon organization, reduced inflammatory signs, and improved echogenicity were observed.

Table no.4: Ultrasonographic Parameters at 8 Weeks

Parameter	Treatment Group	Control Group	p-value

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Tendon thickness (mm)	6.8 ± 1.2	8.4 ± 1.8	<0.001
Echogenicity score (0-3)	2.4 ± 0.6	1.7 ± 0.8	<0.001
Vascularity score (0-3)	0.8 ± 0.7	1.6 ± 0.9	<0.001
Fiber organization (%)	78.3 ± 12.4	52.7 ± 15.8	<0.001

3.4 Secondary Outcomes

Range of Motion: The treatment group showed significantly greater improvements in range of motion across all measured joints. Mean improvement in affected joint range of motion was 34.7° ± 8.9° in the treatment group evaluated to 21.2° ± 7.4° in the control group ($p<0.001$).

Return to Activity: Participants in the treatment group returned to normal activities significantly earlier than controls (6.2 ± 1.8 weeks vs 9.4 ± 2.3 weeks, $p<0.001$).

Patient Satisfaction: Treatment group participants reported higher satisfaction scores on a 10-point scale (8.7 ± 1.2 vs 6.4 ± 1.8, $p<0.001$).

3.5 Safety and Negative Events

No notable adverse events were reported in either group. In the therapy group, 3 individuals (9.7%) experienced mild skin erythema, which disappeared in 24 hours without any treatment. No patients stopped treatment because of side effects.

DISCUSSION

This randomized controlled study shows that when combined with conventional physiotherapy care, photo-biomodulation therapy using particular wavelength LED arrays considerably speeds up tendon healing and improves functional outcomes. There is compelling evidence from the research that PBMT is clinically effective in treating acute tendon injuries.

4.1 Reduction of Pain and Enhancement of Function

The significant pain reduction seen in the PBMT group is consistent with prior studies showing the analgesic properties of photo-biomodulation (Bjordal et al., 2003). The mechanism behind pain alleviation likely involves modulation of nerve conduction, decreased inflammatory mediator production, and increased endorphin release (Chow et al., 2009). The persistent pain reduction seen at 12-week follow-up indicates that the therapeutic benefits endure even after the course of treatment.

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DASH scores, which are used to evaluate key functional gains, demonstrate the real clinical advantages of PBMT. These advances lead to real gains in patients' capacity to carry out everyday tasks and get back to their jobs or athletic pursuits. Our results' clinical significance is supported by the fact that the observed functional improvements surpass the minimal clinically significant difference for the DASH questionnaire (Franchignoni et al., 2014).

4.2 Ultrasonographic Proof of Improved Healing

The ultrasonographic results offer unbiased proof of better tendon healing in the PBMT group. Improved tendon organization, decreased thickness, and increased echogenicity are signs of faster tissue remodeling and maturation. These results corroborate prior animal investigations that demonstrated increased collagen production and better tendon architecture after PBMT (Elias et al., 2013).

At first, the lower vascularity scores in the treatment group may seem paradoxical since enhanced blood flow is usually linked to recovery. However, the lower vascularity probably indicates that the inflammatory phase has subsided and that the healing process has moved into the remodeling phase, which is defined by less hypervascularization (Sharma & Maffulli, 2006).

4.3 Action Mechanisms

This research makes use of the ideal absorption properties of both red (660 nm) and near-infrared (850 nm) light using a dual-wavelength methodology. Red light is mostly absorbed by cytochrome c oxidase in the mitochondrial respiratory chain, which increases ATP synthesis and cellular metabolism (Karu, 2010). Near-infrared light has the potential to penetrate tissues more deeply and have further effects on nitric oxide release and vasodilation (Lohr et al., 2009).

The improved healing observed in our research is likely due to a combination of cellular processes, such as increased ATP synthesis, improved protein synthesis, better cellular proliferation, and modulation of inflammatory responses (Avci et al., 2013). These mechanisms work together to promote quicker tissue repair and better functional outcomes.

4.4 Implications for Practice

The results of this study have substantial therapeutic implications for treating tendon injuries. LED arrays provide a non-invasive, affordable add-on therapy that can greatly enhance patient outcomes through PBMT. With few side effects, the treatment is well tolerated and appropriate for usage in a variety of clinical settings.

The treatment group's rapid return to activity has significant socioeconomic consequences, since it may result in a decrease in healthcare expenditures and lost productivity brought on by extended disability. For acute tendon injuries, healthcare practitioners should think about including PBMT in their therapy regimens.

4.5 Constraints

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There are a number of restrictions that need to be recognized. The research was carried out at only one location, which may restrict its generalizability. The evidence base would be strengthened by multi-center trials. Second, although ultrasonography assessment offers useful objective information, further imaging methods like elastography or MRI may offer more insights into tendon healing.

Although sufficient for determining short-term outcomes, the 12-week follow-up period may not account for recurrence rates or long-term consequences. To determine the longevity of treatment outcomes, longer follow-up investigations are necessary. Moreover, the study participants were fairly similar, and the results may change across different populations or injury kinds.

4.6 Possible Paths for Further Investigation

Future research should prioritize improving treatment regimens, such as examining various wavelength combinations, power densities, and treatment schedules. Comparative trials comparing LED-based PBMT against traditional laser therapy will help determine the comparative effectiveness of different light sources.

Examining biomarkers related to tendon repair may shed light on the processes underlying PBMT and aid in the recognition of patients who are most likely to respond to therapy. Furthermore, cost-effectiveness studies would help inform clinical decision-making and the creation of healthcare policy.

CONCLUSION

In individuals with acute tendon injuries, photobiomodulation therapy employing particular wavelength LED arrays considerably speeds up tendon healing and enhances functional results, according to this randomized controlled trial. When compared to traditional treatment alone, the treatment showed higher effectiveness in a variety of outcome indicators, including pain relief, functional improvement, and measurable ultrasonic healing factors.

As a successful complementary therapy for severe tendon injuries, the results support integrating PBMT into clinical practice. Due to its non-invasive character, high safety profile, and remarkable clinical advantages, the treatment is a tempting option for both patients and healthcare professionals.

In order to improve patient outcomes and speed up the return to normal function, healthcare practitioners who treat tendon injuries should think about integrating LED-based photobiomodulation therapy into complete treatment regimens.

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CONFLICT OF INTEREST

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The authors declare no conflicts of interest related to this study.

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