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Photobiomodulation Therapy in Carpal Tunnel Release: A Randomized Control Trial

Jia Peng Chuah, MS Orth,¹ Saw Sian Khoo, MS Orth,¹
 Tze Yang Chung, MRehabMed,² and Gunasagaran Jayalethchumi, MS Orth¹

Abstract

Background: Carpal tunnel release (CTR) is widely accepted as an effective treatment for carpal tunnel syndrome. However, the recovery is often delayed and incomplete. Photobiomodulation therapy (PBMT) produces a nonthermal effect on living tissues; it promotes healing, remodels and reduces inflammation of an injured nerve. The purpose of this study was to compare the outcome of CTR between patients who underwent post-operative PBMT and without PBMT.

Materials and methods: We recruited 105 patients who had open CTR from January 2019 to January 2021. Fifty-six patients fulfilled the study criteria and were randomized into two groups: with PBMT ($n=28$) and without PBMT ($n=28$). Demographic and clinical data were obtained preoperatively. The PBMT group had ten 3-min sessions over 3 weeks using 808 nm, 50 mW PBMT to deliver 9 J per session to the CTR incision scar. Clinical outcomes were assessed at 1, 3, and 6 months postoperatively. Data analysis was performed with SPSS software.

Results: There were significant improvements in the Functional Status Scale in the Boston Carpal Tunnel Questionnaire ($p=0.018$) and pain (visual analogue scales) in the morning ($p=0.019$) at 1 month postoperatively in the PBMT group compared with the non-PBMT group. Improvement of tip pinch strength at 3 months ($p=0.022$) and 6 months ($p=0.024$), lateral pinch strength at 1 month ($p=0.042$) and 3 months ($p=0.05$), and tripod pinch strength at 3 months ($p=0.005$) was significantly better in the PBMT group. Thumb 2-point discrimination (2PD) at 3 months ($p=0.018$) and 6 months ($p=0.016$) and index finger 2PD at 3 months ($p=0.039$) were also significantly improved in the PBMT group. There were no side effects of PBMT reported.

Conclusions: Patients who underwent PBMT post-CTR had better outcomes. PBMT may be a valuable adjunct to post-CTR care.

Keywords: carpal tunnel syndrome, nerve regeneration, photobiomodulation, laser therapy, low-level laser therapy

Introduction

CARPAL TUNNEL SYNDROME (CTS) can be classified into mild, moderate, or severe.¹ Treatment of CTS is based on the severity of neuropathy. In mild-to-moderate CTS, conservative treatment is the treatment of choice.^{1,2} In severe-to-extreme severe CTS, carpal tunnel release (CTR) is

indicated.^{1,3} Unfortunately, in severe CTS, postoperative patients experience delayed recovery of symptoms and function.

Various modalities are available for treating mild-to-moderate CTS with good clinical and functional outcomes, such as rest, vitamins B6 and B12, nonsteroidal anti-inflammatory drugs, lifestyle and workplace modification,

¹National Orthopaedic Centre of Excellence for Research and Learning (NOCERAL), Department of Orthopaedic Surgery, Faculty of Medicine, Universiti Malaya, Kuala Lumpur, Malaysia.

²Department of Rehabilitation Medicine, Faculty of Medicine, Universiti Malaya, Kuala Lumpur, Malaysia.

orthotic support, nerve and tendon gliding exercises, acupuncture, ultrasound, magnet therapy and corticosteroid injection, or combinations of mentioned.⁴⁻⁸ However, none proved to aid in nerve regeneration. Photobiomodulation therapy (PBMT), also known as low-level laser therapy, is a type of laser that can promote healing, reduce inflammation, and remodel injured nerves through nonthermal means.⁹ It has been studied extensively in animal experiments and human clinical trials with the majority showing positive outcomes.¹⁰⁻²³

PBMT was used in CTS. The peripheral nerve is photosensitive, and a positive biological response was observed in nerves when treated with laser therapy.^{24,25} It proved to be effective in treating patients with mild-to-moderate CTS and/or those who failed other medical or surgical treatments.²⁶⁻²⁸ However, it had lower overall significant result compared with open CTR surgery.²⁹ Few clinical studies reported negative impacts of PBMT on CTS.³⁰⁻³² In 2011, De Pinho Teixeira Alves and de Araújo published positive functional outcomes of PBMT after CTR.³³

With various evidence of nerve regeneration after PBMT in the treatment of nerve repairs,¹⁰⁻²³ we believe that the PBMT would aid in the improvement of patient outcomes after CTR. The purpose of this study was to compare the outcomes between patients who underwent PBMT after CTR with those who did not undergo PBMT after CTR.

Materials and Methods

This study is a prospective, randomized controlled trial approved by the Medical Research Ethics Committee of the University of Malaya Medical Centre (MREC ID No: 201895-6660) conducted from January 2019 to January 2021. The sample size was determined based on the previous study with a Type I error of 0.05 and a Type II error of 0.05, which corresponds to a power of 95%. To account for missing data and lost to follow-up, the sample size was inflated by 20%, resulting in a final sample size of 44 patients.^{33,34}

All patients diagnosed with severe CTS clinically with or without nerve conduction study (NCS) or failed conservative treatment were included in the study. Exclusion criteria were previous surgery, local steroid injection within 6 months, active infection around the wrist, rheumatoid arthritis or other inflammatory disease, and double crush syndrome.

TABLE 1. PARAMETERS OF THE LASER USED FOR PHOTOBIMODULATION

Parameter	
Equipment	LaserCat500, Med Solution
Wavelength (nm)	808
Power (mW)	50
Treatment time (sec)	180
Irradiated area (cm ²)	2.75
Emission mode	Continuous
Number of treatments	10
Energy density (J/cm ²)	3.3
Emitted energy per session (J)	9
Total emitted energy for 10 days (J)	90



FIG. 1. Application of PBMT along the CTR scar. CTR, carpal tunnel release; PBMT, photobiomodulation therapy.

The patients were randomized into CTR with PBMT (Group 1) or CTR without PBMT (Group 2) using a randomization sequence, which was created using Microsoft Excel with a 1:1 allocation using random block sizes of four. Classic open CTR technique without neurolysis was performed under wide-awake local anesthesia with no tourniquet for all patients. After CTR, the PBMT group received laser therapy, whereas the control group did not.

The PBMT protocol of this study was aimed to deliver a treatment dose of 3.3 J/cm² per session, totaling 90 J after the 10 sessions (Table 1). We used 808 nm wavelength and 50 mW power to produce the treatment dose, which was delivered by LaserCat500 machine via an interchangeable treatment tip (MS2) transcutaneously along the CTR incision scar for 3 min (Fig. 1). Group 1 underwent 10 sessions of PBMT within 3 weeks post-CTR. Both groups underwent similar postoperative care, which consisted of analgesia, postoperative tendon and nerve gliding exercises,^{35,36} and wound care management (Table 2).

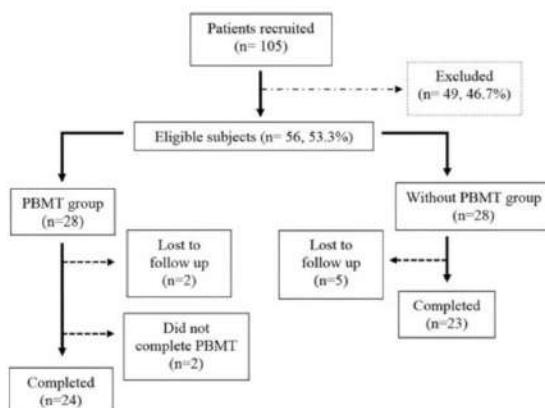
Preoperatively, demographic data, self-reported measures, strength and sensory assessment were collected, and NCS was performed. Demographic data included age, gender, hand dominance, smoking habit, body mass index (BMI), occupation, underlying medical illness, and duration of symptoms. We gathered self-reported measures using the Boston Carpal Tunnel Questionnaire (BCTQ) and visual analogue scales (VAS) in the morning and night. Strength

TABLE 2. POSTOPERATIVE CARE AND REHABILITATION

Analgesia	Paracetamol 1 g QID + celecoxib 200 mg BD for a week
Stretching program	Tendon and nerve gliding exercise a week after surgery ^{35,36}
Orthosis	None
Wound care	Wound inspection on day 2 + removal of suture on day 14

BD: QID.

PBMT IN CTR

**FIG. 2.** Flowchart of the study. *n*=number of patients.

assessments consist of grip strength using a JAMAR® dynamometer and pinch strength (tip pinch, lateral pinch, and tripod pinch) using a pinch meter. Finally, we performed a sensory assessment using 2-point discrimination (2PD). The outcome was reassessed at 1, 3, and 6 months postoperatively. In the 6th month, another NCS was repeated.

Data were collected, tabulated, and analyzed with SPSS Version 22. Descriptive data are expressed as mean, standard deviation, frequency, and percentages (%) as appropriate. An independent *T*-test was used to compare the continuous data between the two groups. Chi-square or Fisher's exact test was used for categorical data. A value of *p*<0.05 was considered statistically significant. The data collected were analyzed using a per-protocol basis.

Results

We evaluated 105 patients who were planned for CTR and 56 of them fulfilled the study criteria. Two patients were

lost to follow-up and two patients did not complete PBMT in Group 1; five patients were lost to follow-up in Group 2. Twenty-four patients completed the study in Group 1 and 23 patients in Group 2 (Fig. 2).

The mean age of the participants was 57.16 years. There was a female predominance in the study (83.9%, *n*=47). The mean BMI of participants was 27.94 kg/m². The associated medical conditions include diabetes mellitus (27%), hypertension (32%), dyslipidemia (23%), and hypothyroidism (4%). Most of the participants were housewives (27%), followed by teachers (21%), desk job workers (16%), nurses (9%), and chefs and kitchen assistants (7%). Majority of participants presented after 1–2 years of symptoms (34%). The demographic parameters and preintervention status of both groups were comparable in this study (Table 3).

The clinical outcomes at 1, 3, and 6 months postoperatively were compared with preoperative outcomes. The analysis of self-reported measures showed significant improvement in Functional Status Scale (*p*=0.018) and morning VAS (*p*=0.019) at 1 month postoperatively. However, all self-reported measures were comparable in both groups at 6 months postoperatively (Table 4). This showed that patients with PBMT had earlier resolution of symptoms.

Both groups had comparable grip strength improvements throughout the study. The patients in the PBMT group showed better improvements in tip pinch at 3 months postoperatively (*p*=0.022) and at 6 months postoperatively (*p*=0.024). Lateral pinch and tripod pinch were also better in the PBMT group at 3 months postoperatively (*p*=0.05, *p*=0.005), but no differences at 6 months postoperatively (Table 4). This showed that patients with PBMT had significant improvement in pinch strength postoperatively.

The patients in the PBMT group showed better improvement of thumb 2PD at 3 months (*p*=0.018) and 6 months postoperatively (*p*=0.016) and index finger 2PD at 3 months postoperatively (*p*=0.039) compared with the

TABLE 3. DEMOGRAPHICS AND CLINICAL PARAMETERS OF GROUP 1 AND GROUP 2

Variable	Group 1 (with PBMT)		Group 2 (without PBMT)		<i>p</i>
	n (%)	Mean (SD)	n (%)	Mean (SD)	
Age (years)		55.6 (14.62)		58.7 (18.11)	0.483 ^a
Gender					
Male	4 (44.4)		5 (55.6)		0.716 ^b
Female	24 (51.1)		23 (48.9)		
Nonsmoker	27 (49.1)		28 (50.9)		1.000 ^c
BMI		29.7 (6.85)		26.2 (4.94)	0.034 ^a
Hand dominance					
Right	27 (50)		27 (50)		1.000 ^c
Left	1 (50)		1 (50)		
Duration of symptoms (months)		45.8 (58.05)		37.9 (43.19)	0.566 ^a
Preoperative NCS severity					
Normal	3 (5.4)		0 (0)		0.390 ^c
Mild	2 (40.0)		3 (60.0)		
Moderate	5 (45.5)		6 (54.5)		
Severe	14 (58.3)		10 (41.7)		

^aIndependent *T*-test.

^bChi-square test of independence.

^cFisher's exact test.

BMI, body mass index; NCS, nerve conduction study; PBMT, photobiomodulation therapy; SD, standard deviation.

TABLE 4. COMPARISON OF CLINICAL PARAMETERS WITH TIME BETWEEN GROUP 1 AND GROUP 2

Variable	Group 1 (with PBMT)	Group 2 (without PBMT)	p
SSS			
0 Month	28.50 (8.93)	25.25 (9.68)	0.197
1 Month	-14.00 (8.52)	-9.87 (8.87)	0.103
3 Months	-14.85 (8.63)	-11.50 (9.76)	0.214
6 Months	-15.50 (8.86)	-11.87 (10.14)	0.187
FSS			
0 Month	19.32 (6.04)	17.71 (5.73)	0.312
1 Month	-6.88 (5.31)	-3.57 (3.95)	0.018*
3 Months	-8.85 (5.32)	-6.05 (5.28)	0.075
6 Months	-9.12 (5.64)	-6.39 (5.95)	0.107
VAS (morning)			
0 Month	3.61 (2.81)	2.00 (2.85)	0.038
1 Month	-3.50 (2.79)	-1.57 (2.76)	0.019*
3 Months	-3.38 (2.71)	-2.05 (3.02)	0.112
6 Months	-3.54 (2.79)	-2.13 (3.00)	0.096
VAS (night)			
0 Month	4.29 (3.77)	3.36 (3.85)	0.366
1 Month	-4.15 (3.73)	-3.30 (3.78)	0.433
3 Months	-4.04 (3.68)	-3.36 (3.92)	0.716
6 Months	-4.15 (3.72)	-3.78 (3.92)	0.735
Grip strength			
0 Month	16.25 (7.64)	14.46 (5.73)	0.327
1 Month	-4.77 (5.90)	-4.24 (5.00)	0.751
3 Months	-1.22 (4.42)	-1.88 (5.76)	0.697
6 Months	0.58 (4.94)	0.30 (5.93)	0.861
Tip pinch			
0 Month	1.19 (0.94)	1.39 (1.05)	0.444
1 Month	-0.05 (0.71)	-0.26 (0.69)	0.317
3 Months	0.45 (0.96)	-0.22 (0.97)	0.022*
6 Months	0.48 (1.00)	-0.10 (0.65)	0.024*
Lateral pinch			
0 Month	2.79 (1.42)	2.96 (1.17)	0.628
1 Month	0.06 (0.89)	-0.57 (1.07)	0.042*
3 Months	0.68 (0.89)	-0.02 (1.23)	0.050*
6 Months	0.79 (1.11)	0.34 (1.06)	0.154
Tripod pinch			
0 Month	1.61 (1.23)	2.04 (1.10)	0.183
1 Month	-0.17 (0.86)	-0.61 (0.84)	0.101
3 Months	0.44 (1.06)	-0.50 (0.74)	0.005*
6 Months	0.60 (1.30)	0.02 (0.94)	0.088
2PD thumb			
0 Month	10.46 (6.16)	8.81 (5.70)	0.308
1 Month	-2.64 (3.76)	-1.57 (3.59)	0.348
3 Months	-4.41 (5.15)	-1.00 (2.19)	0.018*
6 Months	-4.23 (5.09)	-1.27 (2.35)	0.016*
2PD index			
0 Month	9.00 (5.09)	8.37 (5.88)	0.683
1 Month	-1.82 (2.87)	-1.05 (3.54)	0.437
3 Months	-2.24 (3.65)	-0.19 (1.28)	0.039*
6 Months	-2.57 (3.91)	-1.00 (2.51)	0.119

*Significant differences between the two groups.

2PD, 2-point discrimination; FSS, Functional Status Scale; SSS, VAS, visual analogue scales.

control group (Table 4). This showed that patients in the PBMT group had significant improvement in sensation at median nerve distribution.

There were no side effects reported because of the administration of PBMT in this study. In addition, the patients in Group 1 were found to return to work earlier compared with those in Group 2 (27 weeks vs. 38 weeks).

Discussion

The management of CTS is determined by the severity of neuropathy. In mild-to-moderate CTS, conservative treatment is the treatment of choice.¹ When managing CTS conservatively, poor outcomes have been linked to a duration of symptoms lasting over a year, severe night symptoms with a VAS score higher than 5/10, a positive Phalen test, thenar atrophy, and diabetes mellitus.^{3,39} In this study, 74% of patients had symptoms lasting over a year, 41% had severe night symptoms with a VAS score higher than 5/10, 44% had a positive Phalen test, 62% had thenar atrophy (62%), and 27% had diabetes mellitus.

CTR is widely regarded as the most effective treatment for CTS with excellent short-term results. CTR is indicated for moderate-to-severe CTS patients and those who are refractory to conservative treatment. Complete resolution of symptoms is seen in 60.6% of patients and up to 35% experienced only partial recovery at 7–9 months after open CTR.³⁸ It was reported that 70–90% of patients have good to excellent long-term outcomes following CTR.⁴ The positive effects of CTR were reported to persist up to a period of 9 years.³⁹ The outcome is independent of patient characteristics and findings of the initial electrodiagnostic test.³⁹ To date, there is still no standard protocol for treating those who experience persistent or residual symptoms after CTR.

This study was designed to propose a therapeutic modality that could expedite the functional recovery of patients who underwent CTR and ultimately achieve better functional outcomes. A comprehensive literature search revealed a paucity of research regarding the efficacy of PBMT after CTR, with only one clinical trial to date investigating this topic. In a randomized controlled trial, De Pinho Teixeira Alves and de Araújo compared the postoperative results of patients who received PBMT versus those who received placebo laser therapy after CTR. The study found that patients who underwent PBMT had better functional outcomes.³³

There were various similarities in our study, namely sample size, surgical technique (open CTR), PBMT treatment protocol, and study methodology. On contrary, we did not use placebo laser therapy in our control group. We used different equipment to deliver PBMT to our patients: a class 1 Gallium-Arsenide (Ga-As) laser device (Laser-Cat500) manufactured by Med Solution in Germany in comparison to aluminum gallium arsenide Ibamed® laser pen. Both devices were able to deliver the same total treatment dose, which is 3 J/cm². Apart from the above mentioned, De Pinho Teixeira Alves and de Araújo delivered the therapy at three points of the carpal tunnel (pisiform bone, middle of the carpal tunnel, and distal limit of carpal tunnel).

We delivered laser therapy along the CTR incision scar to reduce inconsistency and confusion in delivering the

therapy. De Pinho Teixeira Alves and de Araújo evaluated their patients in terms of postoperative symptoms (painful scar, pillar pain, numbness, night-time pain, palmar pain), Tinel sign, time taken to return to activities of daily living or to work, and NCS. In our study, we utilized various objective clinical measures such as self-reported BCTQ, self-reported VAS, 2PD, grip strength, pinch strength (tip, key or lateral, tripod), and NCS. Among these measures, self-reported BCTQ was considered as the primary outcome.

Despite the differences in clinical outcome measurement, both studies showed earlier and better functional outcomes in patients who received PBMT. De Pinho Teixeira Alves and de Araújo reported earlier cessation of symptom complaints and better normalization of NCS in the PBMT group (70.59% vs. 28.96%). In this study, we found that patients who received PBMT after CTR experienced resolution of CTS symptoms earlier, improved strength of median innervated muscles, improved median nerve distribution sensation, and earlier return to function compared with the non-PBMT group. However, we found that the electrophysiological measures of our patients were not statistically significant.

The NCS result of our studies could be affected by poor turnup rate for repetition of NCS at 6 months because of movement control order during the COVID-19 pandemic. Despite not being statistically significant, the PBMT group showed promising improvement compared with the control group. There were no side effects reported as a result of the administration of PBMT in this study, and this finding is consistent with all previous clinical studies using PBMT.^{18–29,33} The findings of this study added to the growing body of evidence supporting PBMT as a treatment modality, which improves nerve recovery. Based on the results of this study, we recommend the administration of PBMT for all patients post-CTR.

Our study has two main limitations: the absence of double-blinding, which makes it challenging to rule out the potential placebo effect in patients who received PBMT, and the short duration of the study. We hypothesize that a more significant outcome could have been observed at 1 or 2 years postoperation. Hence, it is important to consider these limitations when interpreting the results. Further research with longer follow-up periods and double-blinding is warranted to confirm our findings.

Conclusions

Patients who received PBMT after CTR experienced earlier amelioration of CTS symptoms, as well as improvements in median nerve distribution sensation, muscles strength of median nerve innervated muscles, and faster return to function when compared with those who did not receive PBMT. The findings suggest that PBMT may be a valuable adjunct to post-CTR care.

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Authors' Contributions

J.P.C.: Conceptualization, methodology, investigation, data curation, formal analysis, writing—original draft preparation, visualization. G.J.: Conceptualization, methodology, supervision, writing—reviewing and editing, visualization. S.S.K.: Methodology, writing—reviewing and editing, visualization. T.Y.C.: Methodology, investigation, writing—reviewing and editing.

Author Disclosure Statement

No competing financial interests exist.

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Address correspondence to:
Jia Peng Chuah, MS Orth
National Orthopaedic Centre of Excellence
for Research and Learning (NOCERAL)
Department of Orthopaedic Surgery
Faculty of Medicine
Universiti Malaya
Lembah Pantai
Kuala Lumpur 50603
Malaysia

E-mail: chuahjp@gmail.com

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