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Immediate pain relief effect of low level laser therapy for sports injuries: Randomized, double-blind placebo clinical trial

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ABSTRACT

Objectives: To determine the immediate pain relief effect of low-level laser therapy on sports injuries in athletes and degree of pain relief by the therapy.
Design: Double-blind, randomized, comparative clinical study.
Methods: Participants were 32 college athletes with motion pain at a defined site. Participants were randomized into two groups in which the tested or placebo laser therapy was administered to determine pain intensity from painful action before and after laser irradiation, using the Modified Numerical Rating Scale. The post-therapeutic Modified Numerical Rating Scale score was subtracted from the pre-therapeutic Modified Numerical Rating Scale score to determine pain intensity difference, and the rate of pain intensity difference to pre-therapeutic Modified Numerical Rating Scale was calculated as pain relief rate.
Results: Low-level laser therapy was effective in 75% of the laser group, whereas it was not effective in the placebo group, indicating a significant difference in favor of the laser group ($p < 0.001$). Pain relief rate was significantly higher in the laser group than in the placebo group (36.94% vs. 8.20%, respectively, $p < 0.001$), with the difference in pain relief rate being 28.74%.
Conclusions: Low-level laser therapy provided an immediate pain relief effect, reducing pain by 28.74%. It was effective for pain relief in 75% of participants.

1. Introduction

Sports injuries constitute a serious problem for many athletes and others who participate in sports because they cause pain and dysfunction, resulting in the inability to continue sports activities. Various physical therapies, including electrotherapy, thermotherapy, cryotherapy, and phototherapy, have been used to alleviate symptoms of sports injuries such as pain.[1–3] Low-level laser therapy (LLLT) has been clinically introduced as one of such physical therapies.

LLLT has been examined in clinical research and reported to be effective for its long-term effect on many diseases in the general adult population.[4–6] Bjordal et al.[7] reported that a single session of LLLT relieved tenderness at the affected site in patients with Achilles tendinitis, and they demonstrated both immediate and long-term effects on injuries in the general adult population.

Studies on the effect of LLLT on sports injuries in athletes are limited to the reports of its effect on sprained ankles[8] and Achilles tendinopathy.[9] In both of these studies, the effect of LLLT was the same as was observed in the general adult population. In the study by Stergioulas[8] in patients with sprained ankles, LLLT that was given twice daily significantly alleviated edema at 24–72 h as compared with placebo therapy. In another study by Stergioulas et al.[9] in recreational athletes with Achilles tendinopathy, the combination of eccentric exercise and LLLT for 4–12 weeks alleviated

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motion pain as compared with placebo therapy. Thus, LLLT has been demonstrated to alleviate edema and pain associated with sports injuries in a few days to weeks. However, these studies did not provide any data on the immediate pain relief effect of LLLT on sports injuries in athletes.

Because athletes with sports injuries need earlier functional recovery compared to members of the general population, the immediate effect of LLLT is important. Therefore, this study was designed to evaluate whether LLLT provides an immediate pain relief effect on sports injuries in athletes and to determine the extent of pain relief by LLLT.

2. Materials and methods

A double-blind, randomized, placebo-controlled, parallel-group comparison study was performed. Participants were randomly assigned to the laser or placebo group.

Forty-seven college athletes met the following inclusion criteria: participation in intercollege to athletic activities 5 days/week or more; treatment at Osaka University of Health and Sport Sciences Clinic between July 1, 2013, and January 31, 2015 for sports injury; and diagnosis by an orthopedist with an orthopedic sports injury for which LLLT was indicated. LLLT was indicated for sport injuries if the following criteria were met: the injuries were painful in motion; the painful area was defined; LLLT was not contraindicated; and the injuries were not associated with any neurological findings.

Exclusion criteria were the inability to define the painful area and absence of definite motion pain. Of the 47 patients enrolled in the study, 32 with a definite painful area and motion pain were included as participants.

The 32 participants were randomly assigned to one of two groups, in which either LLLT or placebo laser therapy was administered (the laser and placebo groups, respectively) according to an assignment table prepared by the coordinator using computer-generated random numbers. The following additional data were collected for each participant: name and site of injury, and period from injury to therapy (number of days after injury). The laser group includes 9 patients with ankle sprain, 1 patient with navicular stress fracture, 1 patient with plantar fasciitis, 1 patient with patella tendinitis, 1 patient with spondylolysis, 1 patient with shoulder arthroscopic surgery, 1 patient with triangular fibrocartilage complex injury, and 1 patient with proximal thumb avulsion fracture. The placebo group includes 5 patients with ankle sprain, 2 patients with meniscal injuries, 2 patients with elbow medial collateral ligament sprain, 2 patients with Achilles tendinitis, 1 patient with low back pain, 1 patient with lumbar facet arthritis, 1 patient with infraspinatus muscle injury, 1 patient with deltoid muscle injury, and 1 patient with shoulder periarthritis.

The sample size of the study was calculated at 15 per group using a statistical power of 0.9, intergroup difference of 30, standard deviation of 25, and significant level of 5% with reference to the results of Malliaropoulos et al.[10] EZR statistical software[11] (Saitama Medical Center, Jichi Medical University, Japan, http://www.jichi.ac.jp/saitama-sct/SaitamaHP.files/statmedEN.html) was used for calculating the sample size.

This study was performed with the approval of the Research Ethics Committee of Osaka University of Health and Sport Sciences (Approval No. 12-29). Participants who received oral and written explanation of the study and provided written consent to participate were included in the study. LLLT was performed as one of the therapeutic measures after the experiment was completed. Data were collected in the physiotherapy room of Osaka University of Health and Sport Sciences Clinic. None of the participants prematurely discontinued the experiment.

Table 1
Laser parameters.

Wavelength	810 nm (GaAlAs laser)
Frequency	Continuous output
Optical output	180 mW
Spot diameter	0.0007 cm, 0.0005 cm
Spot size	0.0035 cm^2
Power density	51.4 W/cm^2
Energy	5.4 J at each spot
Energy density	1542.85 J/cm^2 at each spot
Treatment time	30 s × 20 times (total 10 min)
Irradiation site	1 cm^2
Application mode	Probe held stationary in skin contact with a 90° angle and slight pressure

Participants in the laser group received LLLT from laser therapy equipment (Softlasery JQ-W1, Minato Medical Science Co., Ltd, Japan) with an output of 180 mW, irradiation time of 30 s, and total irradiation time of 10 min (Table 1). Participants in the placebo group received placebo therapy from a placebo device (detuned laser) with an output of 0 mW, irradiation time of 30 s, and total irradiation time of 10 min. The Softlasery used for this study was contact-type laser therapy equipment with an irradiation area of 0.0035 cm^2. The most painful area during a painful motion was selected as the irradiation site. In order to find the most painful area, participants were asked to explain the most painful motion during their daily or athletic activities. Then participants were asked to identify the most painful area by their index finger during the movement.

Because the study was double-blinded, the measurer and participants were blinded as to whether they used the actual or placebo laser equipment. The output, irradiation time, and total irradiation time of the laser therapy equipment were setup by the coordinator before each participant entered the physiotherapy room. The measurer left the physiotherapy room before the coordinator setup the laser therapy equipment and was call back after the setup. Each participant operated the laser equipment independently after receiving instructions on how to use it by the coordinator. Irradiation site was kept within 1 cm^2. Therefore a laser prove was applied on the most painful area within a 1 cm^2 area for 30 s each time for 20 times, and total irradiation time of 10 min. To ensure participant safety and eliminate participant bias, participants were instructed not to look at the laser light during laser irradiation. The measurer observed the therapy procedure and measured pain intensity of the painful motion before and after laser irradiation in both groups. Pain during the painful motion was measured using the Modified Numerical Rating Scale (MNRS), which is a 10-cm scale from 0 to 10 at 1-cm intervals in millimeters, with 0 representing no pain and 10 representing the worst pain.

Injury sites were classified into upper limbs, lower limbs, and body trunk. The MNRS score after the therapy (post-MNRS) was subtracted from that before the therapy (pre-MNRS) to determine the pain intensity difference (PID). The rate of PID relative to the pre-MNRS was calculated as the pain relief rate (PRR).

$$\text{PID} = \text{Pre-MNRS} - \text{Post-MNRS}$$
$$\text{PRR} = \text{PID}/\text{Pre-MNRS} \times 100$$

Statistical analysis was performed using SPSS 21.0 J for Windows (IBM Corporation, Armonk, NY, USA) and EZR. The mean number of days after injury, mean PRR, and the 95% confidence interval (95% CI) were calculated for each group.

The difference in injury sites between the groups was tested using Fisher's exact test, with a significance level of 5%. The difference in the number of days after injury, pre-MNRS, or PRR between the groups was tested using an unpaired *t*-test with a significance level of 5%. When a significant difference in the PRR was observed between the groups, PRR was classified into poor, fair, good,

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