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Laser Therapy in the Treatment of Achilles Tendinopathy: A Pilot Study

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ABSTRACT

Objective: **To test the feasibility of a randomized controlled trial to assess the clinical effectiveness of low-level laser therapy (LLLT) when used in addition to eccentric exercise in the management of Achilles tendinopathy.** ***Background Data:*** **LLLT has emerged as a possible treatment modality for tendon injuries. Over the past 20 years only three human studies have investigated LLLT for Achilles tendinopathy.** ***Materials and Methods:*** **Twenty patients were randomized into an active laser or placebo group; all patients, therapists, and investigators were blinded to allocation. All patients were given a 12-week eccentric exercise program and irradiated three times per week for 4 wk with either an active or placebo laser at standardized points over the affected tendons. Irradiation parameters in the active treatment group were: 810 nm, 100 mW, applied to six points on the tendon for 30 s, for a total dose of 3 J per point and 18 J per session. Outcome measures were the VISA-A questionnaire, pain, and isokinetic strength. Patients were measured before treatment and at 4 and 12 wk. Analysis of covariance was used to analyze data, using the effects of baseline measurements as a covariate.** ***Results:*** **Within groups, there were significant improvements ($p < 0.05$) at 4 and 12 wk for all outcome measures, except eccentric strength for the placebo group at 4 wk ($p = 0.11$). Based on the results of the current study, recruitment of 20 subjects per group would be required to perform an adequately powered study based on minimally important clinical differences in VISA-A scale.** ***Conclusion:*** **This study has demonstrated the feasibility of undertaking a randomized controlled trial of LLLT for Achilles tendinopathy. Conclusions regarding effectiveness cannot be made due to the low statistical power of this pilot study.**

INTRODUCTION

The Achilles tendon is a large thick fibrous structure that attaches to the calcaneus and is formed by the confluence of the gastrocnemius and soleus muscles. It is one of two tendons (together with the patellar tendon) most susceptible to overuse injury and rupture.[1] The term "tendinopathy" indicates pain in the region of the tendon without any indication of the cause. Maffuli et al.[2] advocate the use of this term as a general descriptor of tendon injuries, as "tendinitis" implies that inflammation is present, and "tendinosis" suggests degeneration of the tendon.

Tendon injuries are becoming an ever-increasing burden on the health care system. For example, in New Zealand in 2003, 412 Achilles tendon ruptures cost the Accident Compensation Corporation (ACC) approximately NZ$2 million; furthermore, the incidence is rising.[3]

The tendon's structure has been investigated extensively (for a review see Kibler[4]). One hypothesis for the cause of tendon injuries is repetitive microtrauma or overuse pathology; this is primarily associated with collagen separation, matrix damage, and changes in the biomechanical properties of tendon. This matrix damage is considered to be the primary event, overwhelming the ability of the relevant cells to repair structural damage.[5] It is then plausible that any modality that can stimulate cell metabolism and enhance cell proliferation may aid in the repair or recovery of the tendon.

Low-level laser therapy (LLLT) is the term used to describe the use of low-power lasers and superluminous diodes for the treatment of a variety of medical conditions and has emerged

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as a possible treatment modality for tendon injuries. Accepted effects of LLLT are enhanced ATP production, enhanced cell function, and increased protein synthesis.[6] It has also been shown to have positive effects on reduction of inflammation,[7] increase of collagen synthesis,[8] and angiogenesis.[9] However, the effectiveness of LLLT for the treatment of Achilles tendinopathy in the clinical setting has not been adequately established: since 1988 there have been only three trials investigating the effectiveness of LLLT for the treatment of Achilles tendinopathy.[7,10,11] Poor methodology (possible sources of bias and poor reporting of laser parameters) in the earlier two trials[10,11] weaken the results and therefore the evidence from these two trials must be judged with this in mind. The trial of Darre et al.[10] was inconclusive and showed no significant difference between the treatment and control groups, and Meier and Kerkour[11] compared LLLT against LLLT and infrared (IR), concluding that LLLT and IR were significantly better than LLLT alone. The latest trial[7] studied the effects of LLLT over the first 2 h after a single application and concluded that LLLT was effective in reducing the inflammation and pain associated with Achilles tendinitis. Therefore, there is a need for further well-conducted randomized controlled trials to assess the effectiveness of LLLT for the treatment of Achilles tendinopathy in the clinical setting.

The primary aim of this study was to test the feasibility of the protocol for a randomized controlled trial (RCT) to assess the clinical effectiveness of LLLT as an adjunct to eccentric exercise therapy in the management of Achilles tendinopathy. Data from the feasibility study were used to conduct a power analysis for the RCT.

MATERIALS AND METHODS

This was a feasibility study for a prospective, randomized, placebo controlled, double-blinded trial, performed at the Otago School of Physiotherapy Clinics, Dunedin, New Zealand. The Lower South Regional Ethics Committee of New Zealand gave approval for this study.

Patients were recruited by placing an advertisement in the local newspaper. Forty-five people registered interest and all were assessed against the inclusion and exclusion criteria by the principal investigator (ST). The first 20 consecutive patients who fit the inclusion criteria were included in the study; informed consent was obtained from all participants prior to commencing the trial. The principal investigator, blinded to group allocation, performed the initial assessment and evaluation of baseline and follow-up outcome measures at 4 and 12 wk. A different physiotherapist, also blinded to group allocation, performed the 12 treatment sessions over the first 4 wk (the treatment period). All participants were instructed to undertake a program of heavy load eccentric exercises and to complete a compliance log over the 12-week period. In addition participants were randomly allocated to one of two groups and were irradiated three times per week for 4 wk with either a placebo or active laser treatment. The exercises and laser treatment were given in conjunction with each other over the first 4 wk. The laser was given on completion of the exercises for the 12 sessions the patient spent with the treating therapist.

Inclusion criteria

Included were patients between 18 and 65 years of age with a diagnosis of Achilles tendinopathy based on accepted diagnostic criteria, as assessed by an experienced physiotherapist or physician, and who had not received treatment within the last 3 months.

Exclusion criteria

These were: contraindications to LLLT to the area of the Achilles tendon;[12] comorbid musculoskeletal or serious conditions that may have confounded treatment or anticipated recovery; use of NSAIDs; steroid injections or surgery for the condition; insertional tendinopathy or bursitis (retrocalcaneal or Achilles, as determined by clinical examination); neurological signs; and adverse neural tension[13] affecting the sciatic or sural nerves.

Randomisation

A computer-generated list of random numbers was produced and the clinic receptionist randomized subjects into one of two groups by asking them to select any one of 20 identical opaque sealed envelopes. The envelopes contained a study number and a group number, 1 (placebo) or 2 (laser). The group number corresponded to the setting of a switch on the laser unit. Neither the principal investigator, the treating physiotherapist, nor the patient had any knowledge of which group was receiving the active laser treatment.

Laser protocol

The therapy system used in this trial was the Thor DD Laser Therapy Unit (Thor International Ltd., Chesham, Buckinghamshire, England), a class 3B laser with an 810-nm 100-mW infrared probe, spot size of 0.0364 cm^2, and power den-

Table 1. Subject Demographic Data and Baseline Measurements

	Laser group (n = *10*) *mean (SD)*	*Placebo group* (n = *10*) *mean (SD)*	p *value*
Age (years)	41.4 (7.6)	42.5 (8.5)	0.763
Gender (F/M)	7/3	4/6	NA
VISA-A	57 (16.7)	56.3 (19.8)	0.933
Pain (mm on VAS)	47.8 (25.9)	39 (20.2)	0.409
Concentric strength (Nm)	137.8 (48.4)	124.1 (55.0)	0.564
Eccentric strength (Nm)	190.9 (58.5)	180.1 (67.2)	0.708

Table 2. Within-Group Mean Differences for Outcomes between Baseline and Follow-Up Periods

		4 weeks: Difference between means (95% CI)	p	*12 weeks: Difference between means (95% CI)*	p
VISA-A	Placebo	−21.4 (−30.4 to −12.4)	0.000	−21.2 (−29.6 to −12.9)	0.000
	Laser	−18.9 (−34.8 to −3.1)	0.024	−25.2 (−45.8 to −4.6)	0.022
Pain	Placebo	17.2 (4.5–29.9)	0.013	20.0 (5.7–34.3)	0.011
	Laser	22.6 (1.2–44.0)	0.040	30.9 (8.2–53.6)	0.013
Concentric strength (Nm)	Placebo	−43.0 (−79.0 to −7.1)	0.024	−84.2 (−125.8 to −42.5)	0.001
	Laser	−34.0 (−62.4 to −5.2)	0.025	−59.2 (−84.6 to −33.9)	0.001
Eccentric strength (Nm)	Placebo	−31.5 (−71.8 to −8.7)	0.110	−79.2 (−132.8 to −25.6)–49.8	0.009
	Laser	−33.1 (−62.4 to −3.7)	0.031	(−77.0 to −22.6)	0.003

For VISA-A, concentric strength and eccentric strength negative values denote improvement. For pain, positive values denote improvement.

sity of 2.375 W/cm^2. Laser treatment was delivered with the subject prone with their foot over the end of the treatment plinth, and the ankle plantargrade. The contact method was applied to three standardized points on either side of the Achilles tendon (six in all: at the insertion, 2 cm proximal, and 4 cm proximal) for 30 s, for a total dose of 3 J per point and 18 J per session. Treatment was given three times per week for 4 wk.

Exercise protocol

Patients were instructed on how to perform a unilateral heavy load eccentric plantarflexion training program for six sets of 15 repetitions, twice per day, 7 d per week for 12 wk.[14] Exercises were performed on a step and individually targeted the gastrocnemius and soleus by being performed (for three sets of the exercise) with the knee held in extension, and (for three sets) in slight knee flexion. Load was added so the patient's symptoms were provoked during the exercise. This program is unique, as it encourages patients to complete the exercise even if they experience pain, and are only allowed to stop (or decrease the applied load) if the pain becomes disabling. When subjects could complete the exercise without pain the load was increased by the addition of extra weight.

Outcome measures

All of the outcomes were measured before treatment 1, after treatment 12 (at 4 wk), and at the 12-week follow-up. The primary outcome measure was the VISA-A questionnaire,[15] developed by the Victoria Institute of Sport and designed specifically for Achilles tendon problems, which is scored on a scale from 0–100 (100 = a totally healthy tendon and 0 = a painful tendon severely impacting function). The amount of pain first thing in the morning (the worst pain) was evaluated by the patients on a 100-mm visual analogue scale (VAS), (0 = no pain and 100 = the worst pain imaginable). Isokinetic measurement of muscle strength (Nm) was also undertaken using a Biodex dynamometer (Biodex Medical Systems Inc., Shirley, New York, USA) at the point when pain began. For this test, patients were seated with 40° of knee flexion and the hip at 110°; strength was measured between 20° of dorsiflexion and 30° of plantarflexion at a speed of 90°/s.[14]

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences software (SPSS 14.0, SPSS Inc., Chicago, IL, USA), with alpha set to 0.05. Normal descriptive statistics of the two groups such as means and standard deviations were calculated.

Table 3. Mean Differences between Groups for Outcomes at the Two Follow-Up Periods

	Week 4: Difference between group means (95% CI)	*Week 12: Difference between group means (95% CI)*
VISA-A	−2.0 (−14.9 to 10.9)	4.6 (−11.7 to 20.8)
Pain (VAS)	0.5 (−18.3 to 19.3)	−5.5 (−27.5 to 16.6)
Concentric strength (Nm)	−3.2 (−42.2 to 35.9)	−19.8 (−62.9 to 23.3)
Eccentric strength (Nm)	6.3 (−33.2 to 45.8)	−25.2 (−77.7 to 27.4)

Covariates appearing in the model are evaluated at the following values: VISA-A initial 56.65; pain initial 43.4; concentric strength initial 130.95; eccentric strength initial 185.56.

For VISA-A, positive values for concentric strength and eccentric strength denote that laser is better than placebo. For pain, negative values denote that laser is better than placebo.

RESULTS

A total of 45 subjects initially expressed interest in the trial; of these, 45 were screened and 20 recruited to the trial. All 20 patients completed the course of treatment as described in the methodology according to group allocation, and were therefore eligible to be included in the statistical analysis. Demographic and baseline data are presented in Table 1; there were no statistically significant differences in baseline data observed between the groups.

Within groups, there was a significant difference ($p < 0.05$) between baseline scores and the two evaluation periods of 4 and 12 wk for all of the outcome measures, except for eccentric strength in the placebo group at 4 wk ($p = 0.11$) (Tables 2 and 3). However, differences between groups were minimal.

The variability of scores within groups was quite large for all outcome measures, and it was difficult to recognize any trends in the data. This is illustrated in Fig. 1, which shows the individual scores for pain and the VISA-A.

DISCUSSION

This study was designed to test the feasibility and provide data for a power analysis for an RCT of the effectiveness of LLLT in the treatment of Achilles tendinopathy; this has been achieved, and our research protocol was demonstrated to be feasible for a fully-powered study. While comparison between the treatment and control groups is of secondary importance at this stage, the ensuing study (and current results) should contribute to the body of evidence surrounding the use of LLLT for the treatment of Achilles tendinopathy.

Using our data it was possible to perform a power analysis for a future adequately-powered RCT with the same methodology. However, given the lack of clear differences between groups (not an unexpected finding for a pilot study), this was based on the minimal clinical important difference (MCID) rather than the results of the study. For the VISA-A, Khan et al.[16] state that 25 points is clinically significant, based on the previous work of Robinson et al.[15] However, the article by Robinson et al. is about the development of the VISA-A and has no mention of a clinically significant change value. As for the VAS for pain, Chow et al.[17] cite a range of previous studies that found 13 mm on a 100-mm scale[18] or 2 points on a 10-point scale to be significant.[19–21] However, MCID has only minimal generalizability across groups, and it has been suggested that it may be best derived from the clinical data (e.g., 75% of the patient population scored a change of 20 points or more).[22] Using this approach with our pilot data, we get an MCID of 15 mm on VAS for pain, and 16 points for VISA-A (i.e., 75% of patients achieved these scores or better). Therefore, for an adequately-powered RCT using the same research design and VISA-A as the primary outcome measure, the number of participants needed in each group (allowing for 20% dropout) would be 20 (SD 20.25, power 80%, type I error 0.05).

Such an RCT is urgently needed in this field, as the clinical effectiveness of LLLT for the treatment of tendinopathy is still somewhat controversial. It is widely accepted that the underlying problem in the tendon is one of degeneration and not inflammation;[23] indeed Lind et al.[24] have shown positive results by reducing or eliminating neovascularization. Some of the known effects of LLLT are anti-inflammatory[7] and increased neovascularization,[9] which would seem to be contrary to the effects desired needed to treat the condition. Other effects that

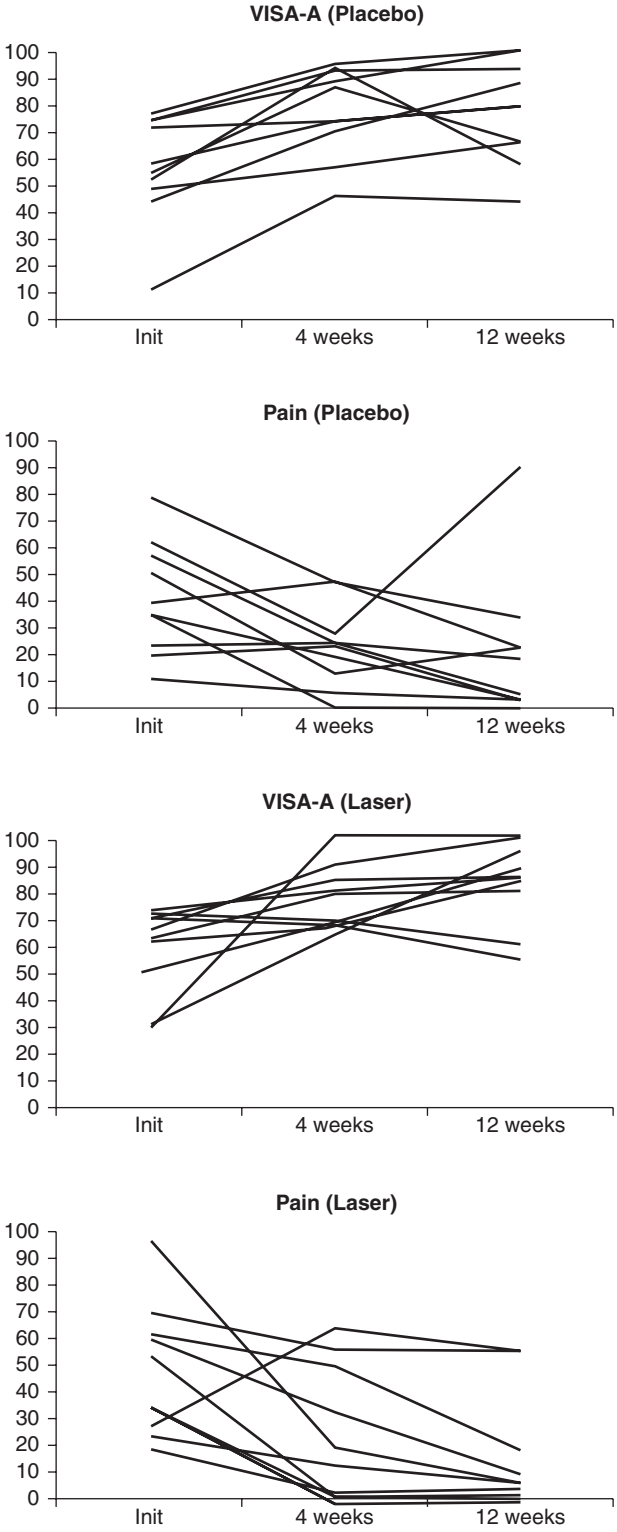

FIG. 1. Individual scores for pain and VISA-A divided into placebo and laser groups.

may contribute to beneficial outcomes are increased collagen synthesis,[8] which would help to address degeneration, and pain relief,[25] which would also be beneficial. To date the clinical evidence regarding LLLT in the treatment of tendinopathy is mixed, and there is a paucity of good RCTs upon which to base any decision. Bjordal et al.[26] found only 16 for inclusion in their review, of which only nine were considered to have used optimal treatment parameters. In particular, there are only three human studies on LLLT in the treatment of Achilles tendinopathy,[7,10,11] and the evidence provided by these is variable. Darre et al.[10] examined only solders (aged 18–22 y), which would be considered an atypical group. In contrast, our subjects had a mean age of 42 y, and they therefore more closely fit the profile for the age of peak incidence,[3] according to epidemiological data. Any comparison with the other two studies is limited, as Meier et al.[11] compared two different protocols of laser and infrared treatments, and Bjordal et al.[7] examined the anti-inflammatory effects over the first 2 hours after application of laser energy.

As the aim of this study was to test the feasibility of the research design, it is pertinent to consider the methodology and the reasoning behind the decisions made. Heavy-load eccentric exercise[14] has emerged as the treatment of choice for Achilles tendinopathy, and we decided to use this as a common intervention for everyone who participated in the study, regardless of group allocation. However, this design measures the effect of the adjunct intervention (in this case LLLT) over and above that of eccentric exercises, and is appealing because, unlike a placebo-controlled explanatory trial, half of the patients are not being denied treatment. Other authors have used this approach: Brown et al.[27] investigated the effectiveness of aprotinin injection in the management of Achilles tendinopathy and had all participants perform eccentric exercises. However, as in our study, while there were improvements in both groups, they failed to show any significant differences between groups, indicating that there was no added benefit from the adjunct therapy.

The selection of the optimal dose in clinical trials of LLLT (or indeed for routine clinical use) is controversial, as often the reporting of parameters has varied in previous studies. However, there is enough information from a previous detailed review by Bjordal et al.[26] to indicate an optimal dose range (or window); in addition, the World Association of Laser Therapy (WALT) website[28] provides dosage recommendations on the energy to be delivered to the skin over the target tendon, and also recommends irradiating most of the pathological tissue in the tendon. These two sources of information thus provide the clinician or clinical researcher a therapeutic window from which to choose. For the current feasibility study, it was decided to use a dose that lay in the middle of the range recommended by Bjordal et al.[26] (0.7–7 J/cm^2); thus we delivered 3 J per point to the skin at six points along the affected tendon. However, the Thor laser system employed here had a 100-mW probe, which although commonly used in routine clinical practice, would have provided an irradiance significantly higher than that recommended by Bjordal et al. (5–100 mW/cm^2).[26] This is then an important consideration for the future RCT, for which it is planned to employ a different probe with a lower irradiance.

The main outcome measures used in this feasibility study were found to be useful and reliable. The primary outcome measure was the VISA-A questionnaire developed by the Victoria Institute of Sport and designed specifically for Achilles tendon problems. It has been shown to be valid and reliable,[15,29] and is often used in Achilles tendon studies.[17,30,31] Visual analogue scales have become an acceptable measurement tool,[32] and the use of a VAS to measure pain has been shown to have a high interclass correlation of 0.95.[33]

This study used a 12-week follow-up period, which was chosen because after 3 mo of heavy-load eccentric exercises, it is expected that the majority of patients would have returned to sport;[14] also the turnaround for collagen synthesis is approximately 100 d,[34] therefore it was considered relevant to compare the groups at this stage.

When attempting to measure a treatment effect between a treated and untreated group on a quantitative outcome measured before and after treatment, one must be aware that baseline values are negatively correlated with change, and more often than not patients with a low score at baseline will improve more than patients with a high score at baseline. In randomized trials, analysis of covariance (ANCOVA) using baseline scores as the covariate is the preferred test,[35] and gives more statistical power to the analysis.[36] This is therefore considered the most appropriate means of analysis for the main study.

CONCLUSION

The current methodology has been shown to be feasible, and the study has provided data to design a future adequately-powered RCT. As this study had low numbers, we cannot make any conclusions regarding the effectiveness of LLLT for the treatment of Achilles tendinopathy; however, the treatment package as a whole provided a significant improvement in all outcome measures ($p < 0.05$) for both groups, a positive note for the physiotherapeutic management of this condition. The facts that there have been few human studies on LLLT for Achilles tendinopathy, and no other studies have been carried out investigating the benefit of adding LLLT to a program of eccentric exercise therapy, indicate that further investigation is needed to assess the effectiveness of this modality.

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