# A Double-blind Clinical Trial of Low Power Pulsed Shortwave Therapy in the Treatment of a Soft Tissue Injury

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**Key words:** Soft tissue injury, pulsed shortwave, electromagnetic radiation, gait analysis, goniometry, evaluation of treatment.

**Summary:** This paper describes the methodology and results of a double-blind trial to assess the efficacy of a commercial low power pulsed shortwave therapy machine in the treatment of lateral ligament sprains of the ankle. A total of 73 patients were randomly allocated to one of two groups and received treatment with a machine which was either functioning normally or was disabled. Their progress was assessed by means of goniometry, volumetric measurements, subjective pain scores and gait analysis. No difference between the two groups due to treatment with active as opposed to disabled machines was detected. The authors conclude by questioning whether such machines should be marketed without sound evidence of efficacy.

**Biography:** Dr A T Barker is a principal physicist in the department of medical physics and clinical engineering at the Royal Hallamshire Hospital in Sheffield. He specialises in research on the biological and clinical effects of electric and magnetic fields and has recently published papers describing clinical trials of pulsed magnetic field therapy for bone non-unions, permanent magnet therapy for soft tissue injuries and on the stimulation of the human brain with large magnetic field pulses. He graduated in electronic engineering at Sheffield University in 1971 and completed his PhD on the analysis of compound nerve action potentials in 1976.

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Mrs L Andrews trained at Queen Margaret College, Edinburgh. She worked at Bangour Hospital, West Lothian, and then moved to Rotherham where she is now superintendent (out-patients). Her particular interests are sports and soft tissue injuries.

Mr W J O'Dowd obtained a degree in physics at the University of Rhode Island (USA). He then spent four years working with the US Coast Guard on various aspects of marine electronics in the US and Germany. Since 1977 he has been working on the evaluation of medical equipment for the DHSS as a member of the department of medical physics and clinical engineering in Sheffield. His main areas of interest and responsibility are electronics and optics as applied to physiotherapy and ventricular defibrillation.

## Introduction

A VARIETY of machines generating 27 MHz electromagnetic energy, in either pulsed or continuous form, have been routinely used by physiotherapists to treat soft tissue injuries for over 50 years. Studies using high power pulsed equipment (predominantly Diapulse), generating peak powers of several hundred watts, suggest that it has several beneficial effects including the acceleration of wound healing (Cameron, 1961, 1964; Goldin *et al,* 1981), haematoma resolution (Fenn, 1969), and reduction of pain and swelling in soft tissue injuries (Wilson, 1972, 1974; Pasila *et al,* 1978; Barclay *et al,* 1983). These effects are claimed to be due to a variety of non-thermal phenomena such as the restoration of the membrane potentials of damaged cells and have been summarised by Hayne (1984). However, it is difficult to differentiate between any non-thermal effect and a thermal response caused by the relatively high average power output (up to 40 W) emitted from machines used in these trials. It has been shown that pulsing the output of a short-wave device, while keeping its mean output power constant, does not decrease the heating effects which remain clearly demonstrable (Silvermann and Pendleton, 1968). An average absorbed power of 40 W would represent over 25% of the mean base metabolic rate of an adult male and over 40% for an adult female (Bell *et al,* 1976) and hence is clearly not insignificant.

Low power pulsed systems such as the Therafield Beta have recently become available, based on pulse widths and repetition rates similar to the high power pulsed systems, but with a maximum average power output of less than 10 mW. They are claimed to give therapeutic results similar to the previous high power machines. Since the low power systems will cause negligible heating compared to that generated by

the body's metabolism they can be used to assess the claims for non-thermal therapeutic effects.

In an attempt to investigate the presence of non-thermal effects produced by pulsed electromagnetic energy when applied to soft tissue injuries, a double-blind clinical trial of the Therafield Beta in the treatment of lateral ligament sprains of the ankle was instigated. This paper presents the results of the study, which began in October 1984, jointly organised by the departments of physiotherapy at the Royal Hallamshire Hospital, Sheffield, and Rotherham District General Hospital, and the department of medical physics and clinical engineering, Royal Hallamshire Hospital.

## Method

Patients of either sex aged between 16 and 65 who had sustained a lateral ligament sprain of the ankle within the previous 36 hours were referred from casualty and entered the trial if they were willing to participate and met the admission criteria as shown in table 1.

**Table 1: Patient admission criteria**

1. Radiographs showed that no bone damage had occurred.
2. Neither ankle had been injured in the previous nine months.
3. There were no other current conditions affecting the feet, ankles or gait.
4. There were no open wounds or skin infections in the lower limbs or feet.
5. Severe vascular disease was not present.
6. The patient was not pregnant.
7. The patient did not wear a pacemaker.
8. The patient was not taking anti-inflammatory or anti-coagulant drugs.
9. The patient had signed a consent form.

### Random Allocation to Active or Control Groups

Patients were allocated a number on entry to the trial in sequential order by the physiotherapist. This number was set on digital switches attached to the treatment machine each time the patient was treated. Depending on the setting of this number the machine either functioned normally (active) or had its output disabled (control), according to a predetermined random sequence unknown to the physiotherapist. Neither the patient nor the physiotherapist was able to detect whether the machine was in the active or control mode.

### Clinical Protocol

Following discussions with the manufacturer, patients received a single session of treatment lasting 45 minutes (active or control) on each of three consecutive days using the Therafield Beta pulsed shortwave electromagnetic unit (day 1 being within 36 hours of injury). The agreed machine settings used throughout the trial were:

Bursts/sec — 640.
Magnetic field — continuous.
Intensity setting — high.

The neutral electrode was not used. Technical details of the machine can be found in the appendix. The patients were positioned in long sitting with the two antennae held on either side of their injured ankle by Velcro straps.

On day 1 the patients were assessed before and after treatment. On days 2 and 3 assessment took place after treatment and on days 8 and 15 the patients were assessed without electromagnetic treatment.

### General Medical Treatment

All patients received the same general medical treatment:

1. A single thickness, low tension Tubigrip support stocking was supplied.
2. Patients were advised to rest with their injured leg elevated whenever possible and were encouraged to move their ankle while resting.
3. They were loaned elbow crutches and instructed not to bear weight on the injured ankle until they returned the following day (day 2). On day 2 they could partially weight-bear if they were able and from day 3 they could choose to keep their crutches, use a stick or bear weight fully. A record was kept of the day on which they stopped using an aid. No gait training other than how to use the crutches was given before day 8 but after this the physiotherapist could instruct the patient as required.
4. Patients were prescribed analgesics (Paramol) by the casualty doctor and were asked to keep a note of usage.
5. Patients were requested not to use ice, sprays or ointments on their injured ankle.
6. Patients who, in the opinion of the physiotherapist, required alternative forms of treatment after day 3 or who were still unable to bear any weight on day 3, were withdrawn from the trial.
7. All patients were reviewed by casualty doctors on day 8 in addition to the normal trial assessment.

### Assessment

The parameters chosen for assessment were range of movement, gait, pain and swelling.

*1. Range of movement*

A Swedish OB goniometer which consists of a circular dial with a gravitational inclination needle was adapted so that it could be attached to the foot. The patient lay supine with the knees held in slight flexion by a standard wooden block, and the ankles positioned over the end of the couch. The goniometer was positioned on the centre of the patient's heel by means of double sided adhesive pads and three readings (to the nearest 1°) were taken alternately for dorsiflexion and for plantarflexion on each ankle using the inclination needle. These readings were averaged and the ratio of the range of movement in the uninjured ankle to the range of movement in the injured ankle was calculated.

*2. Gait*

Gait was assessed by electronically recording the position and timing of the feet while the patient walked along a purpose-designed walkway. The walkway consisted of a plastic mat 6.4 metres x 0.5 metres with attached sensing wires similar to that described by Arenson *et al* (1983) but constructed so that it could be rolled up and installed on any suitably sized floor. Metal foil markers were attached to surgical overshoes worn over bare feet and suitable electronics enabled their position along the walkway to be recorded against time on standard tape cassettes along with a voice channel for patient details. Subsequently these tapes were replayed into a BBC model B microcomputer which calculated the four gait parameters to be described in detail later.

*3. Pain*

Subjective assessment of the pain felt by the patient in the injured ankle during the walkway measurements was made by the patient marking an ungraduated 10 cm line, the ends of

**Table 2: Summary of patient groups**

| Group | Number of patients | Age range (years) | Median age (years) | Sex | Hours from injury to first treatment (median) | Number attending on days | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1 | 2 | 3 | 8 | 15 |
| Active | 34 | 16-55 | 28 | 24M 10F | 16 | 34 | 34 | 34 | 33 | 24 |
| Control | 39 | 16-56 | 30 | 23M 16F | 16 | 39 | 39 | 39 | 35 | 20 |

which were labelled 'no pain' and 'extremely severe pain'. A new line on a separate sheet of paper was used on each occasion so that the patient was unable to see the previous mark. The distance of the mark from the 'no pain' end was recorded in centimetres.

*4. Swelling*

Swelling was measured by water displacement using a purpose-built Perspex tank. This consisted of two identical chambers with an overflow spout in each side 20 cm from the bottom of the tank, based on the design of Nilsson and Haugen (1981) who considered the technique and the errors involved in detail. The dimensions of the base of each chamber were 35 x 16 cm. Both halves were filled with water at a temperature of 29°C $\pm$ 3° C and the excess allowed to run out so that the water levels were the same. The patient placed one foot in each side of the tank, care being taken to ensure the sole of the foot was flat on the bottom and the lower leg was vertical. The water overflow was collected in two graduated measuring cylinders and the two volumes were read to the nearest 5 ml and recorded. Subsequently the ratio of the volume of the injured to the uninjured foot was calculated.

## Results

### The Patient Groups

A total of 82 patients met the admission criteria during a period of five months and entered the trial. Eight patients (five active, three controls) did not return for the three days of treatment and have been excluded from the analysis. One patient in each group was subsequently found to have bone fractures which were not detected on the initial radiographs but were found when the patients were withdrawn from the trial because of lack of progress. They were excluded as not meeting the admission criteria. All the recorded data from the remaining 73 patients were analysed. Seven patients were withdrawn at day 8 (three active, four controls) because they were assessed as requiring additional treatment, but their data from days 1 to 8 have been included in the full analysis. Inevitably some patients failed to return for their later checkups and the attendance figures plus age and sex distributions of the groups are shown in table 2.

### Statistical Analysis of the Data

The data obtained for the control and active groups at each assessment have been compared using the Student's 't' test corrected for unequal variance where necessary. A total of seven measurements have been analysed at each time point. Because of these multiple measurements the likelihood of detecting an apparent difference between the two groups, at a given probability level, is increased even if the groups are in fact identical (Pocock, 1983 p230). Hence, following normal conservative statistical practice, the 'p' values obtained have been multiplied by seven to allow for this multiplicity and the resultant values are shown in figures 1 to 7 (Pocock, 1983; Tukey, 1977). If the 'p' values from the individual 't' tests are required they can be obtained by dividing the quoted figures by seven. Non-parametric tests have also been carried out but the results are not quoted because the 'p' values were always larger than those obtained from the Student's 't' test.

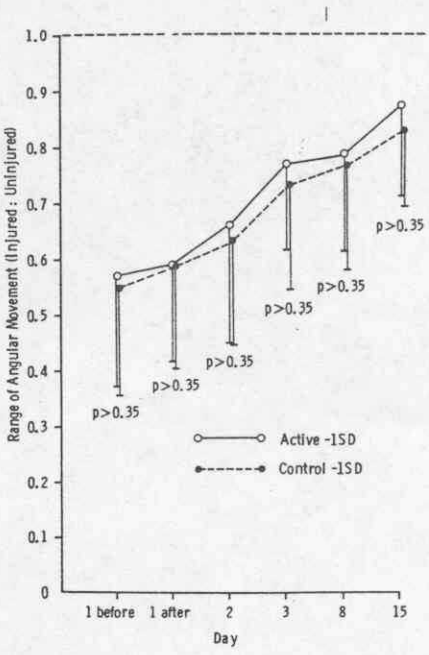


**Fig 1: Goniometry data**

### Goniometry

Figure 1 shows the ratio of range of angular movement in the injured and uninjured ankles for the two groups. As expected the ratio increases, from about 0.55 at day 1 to 0.85 at day 15, but there is no statistically significant difference between the groups.

### Volumetry

Figure 2 shows the ratios of injured to uninjured ankle volume for the two groups. The swelling in both groups increases on days 2 and 3 with the active group appearing slightly worse, even before treatment, although the variability of the data is large throughout as can be seen by the standard deviations, and none of the differences is statistically significant.

### Pain Scores

Figure 3 shows the means of the pain scores for each group. By day 15 the scores had dropped to near zero and the two groups remained closely matched throughout with no statistically significant differences.

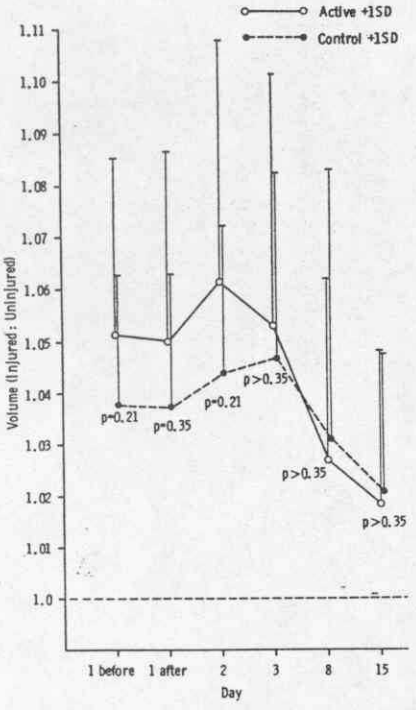


Fig 2: Volumetric data

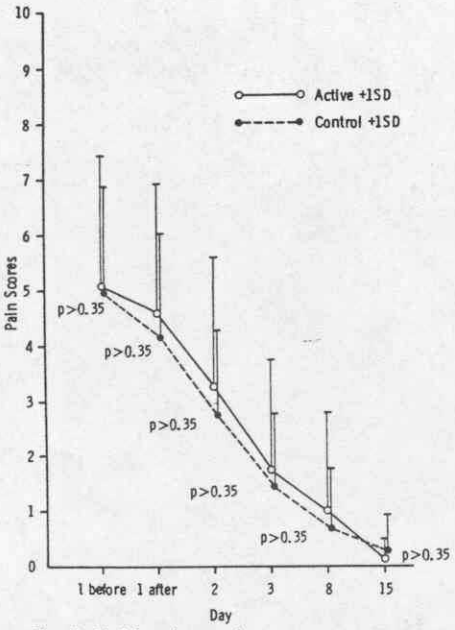


Fig 3: Subjective pain scores

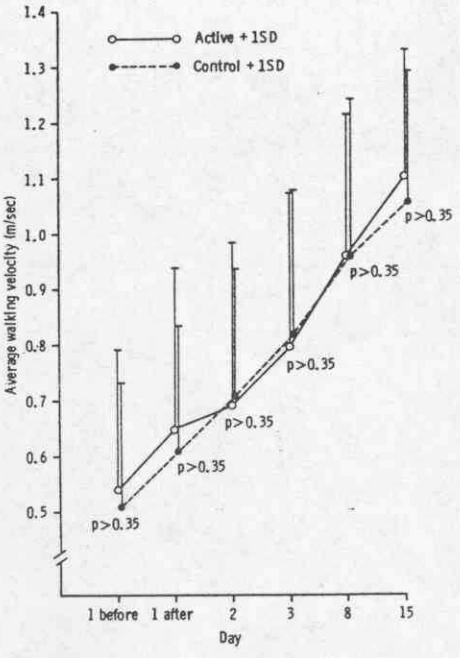


Fig 4: Average walking velocity

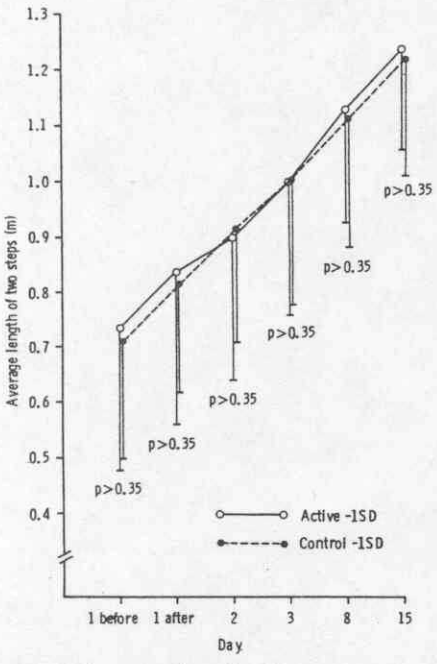


Fig 5: Average length of two steps

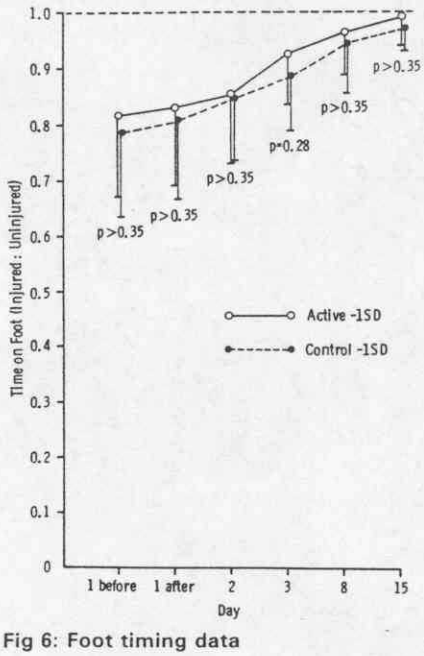


Fig 6: Foot timing data

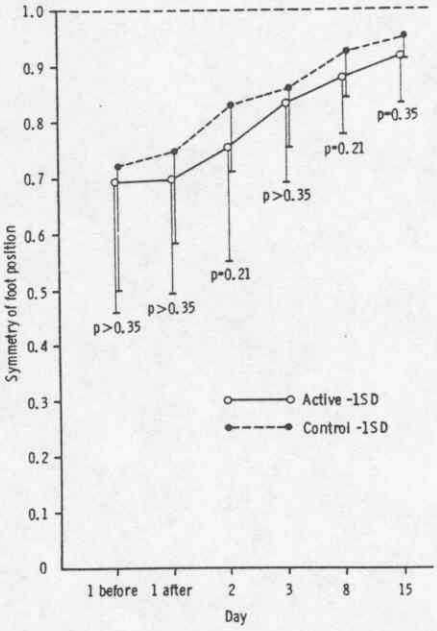


Fig 7: Symmetry of foot position

## Gait Analysis

Four parameters were chosen to try to assess the functional disability caused by the injury. Figure 4 shows the average walking velocities for the two groups and indicates a steady increase in walking speed during the period of observation. Some of the increase will be due to familiarity with the walkway but normal subjects do not show the initial very slow speeds when using the walkway for the first time. Similarly, figure 5 shows the average length of two steps increasing steadily with time from injury and neither parameter reveals statistically significant differences between the two groups.

Two parameters were used to assess the symmetry of gait (the human observer probably detects a limp by looking for asymmetric movement of the body, which is a sensitive assessment but not quantitative). The ratio of time spent on each foot while walking is shown in figure 6. On entry to the trial patients spent, on average, approximately 20% less time on the injured limb compared with the uninjured. As recovery proceeded, time spent on each foot became more equal in both groups.

Figure 7 shows a ratio of symmetry of foot position. Normal subjects move each foot the same distance in front of the other when walking but patients with sprained ankles tend to let their injured limb either lag behind or, less frequently, place it in front of the normal symmetrical walking position. To allow for these two forms of gait the parameter shown in figure 7 has been calculated by measuring the distance between the feet on two successive paces, dividing the shorter by the

longer distance. Both figures 6 and 7 show a steady improvement towards the expected normal ratio of one without significant differences between the groups.

### Additional Data

The median total number of Paramol tablets used by patients in the active group was three (range 0-14) and also in the control group (range 0-12). The median number of days for which a walking aid was used by patients in the active group was three (range 2-14, mean 3.7, and for the control group two (range 2-7, mean 3.3). As previously stated, all patients had been requested to use an aid for the first two days of the trial.

The two physiotherapists who between them saw all the patients were asked to guess whether each patient had been allocated an active or disabled machine, based on their general clinical impressions and the assumption that active machines were efficacious. Of the 37 patients thought to have active machines in fact only 16 did. Of the 36 patients thought to have disabled machines, in fact only 18 did.

### Summary

All the quantitative measurements carried out in this trial have failed to show a statistically significant difference between the active and control groups. Even if the correction for data multiplicity described earlier is not made, no consistent differences between the two groups can be seen. These findings are substantiated by the subjective impression of the trained clinical observers who were unable to identify whether the machine was active or not with greater success than would be expected by chance.

## Discussion

There are a growing number of low power pulsed shortwave therapy units being marketed for which various claims are made, including statements that clinical results are impressive in soft tissue applications.

If this were so, these units would be very useful adjuncts to a physiotherapy department, particularly for community and bedside use. They are light, portable, easy to use and cost considerably less than previously available units although the recommended treatment times are rather long. However, in the case of the soft tissue injuries sustained in a sprain of the lateral ligament of the ankle, we have not been able to demonstrate any measurable or observable effect.

While trials of this nature may be unable to detect small but real treatment effects, the value of any such effects, that cannot be seen in extensive monitoring of some 70 patients, are unlikely to be of clinical significance for the management of a soft tissue injury.

No scientifically sustainable mechanism has yet been proposed to explain the claimed therapeutic benefits of low power pulsed 27 MHz (or, as in the case of the Therafield Beta, in combination with weak low frequency magnetic fields). Hence we must conclude that the manufacturers' claims for the efficacy of this treatment for soft tissue injuries remain unproved and this must cast doubt on the other recommended applications of the technique.

The inability of trials such as this to demonstrate beneficial effects raises an important question. Should treatment devices be marketed without sound evidence of efficacy? Arguably the onus should rest on the manufacturers to provide such evidence, preferably from clinical double-blind trials, before making a device commercially available.

## APPENDIX

*Technical Description of the Therafield Beta*

The Therafield Beta is a portable (6 kg) pulsed shortwave therapy unit. It produces 65 μsec duration bursts of 27 MHz with a settable repetition rate from 10 to 640 bursts per second. The signal is applied to the patient via two electrodes, which can be used either separately or in combination. The electrodes, which have a metal foil surface, need not be in direct electrical contact with the subject. The electrodes are split into three segments and driven in a complex manner (details available from the authors on request). A 'neutral' conducting rubber electrode is also provided which, if used, connects the patient to the zero volt line of the electronics.

In addition to the main output at 27 MHz the unit also produces a weak local low frequency magnetic field from a total of nine ferrite cores built into the two electrodes (40 Hz square wave, maximum peak field at electrode surface = 0.13 mT and 0.02 mT at a distance of 13 mm).

Power input measurements have been made into a dummy load at the trial settings, which correspond to the maximum output from the machine. The available power increases with decreasing load resistance in the range of 1,000Ω to 25Ω with typical figures of 35 mW peak, 1.5 mW average at 1,000Ω; 90 mW peak, 4 mW average at 100Ω and 150 mW peak, 6mW average at 25Ω.


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