A DOUBLE BLIND CROSSOVER TRIAL OF LOW LEVEL LASER THERAPY IN THE TREATMENT OF POST HERPETIC NEURALGIA

Kevin C. Moore*, Naru Hira†, Parswanath S. Kumar‡, Copparam S. Jayakumar§ and Toshio Ohshiro||

*Consultant Anaesthetist, † Consultant in General Surgery, ‡ Consultant in Accident and Emergency Medicine, §Associate Specialist in Accident and Emergency Medicine, The Oldham Group of Hospitals, Oldham Lancashire, UK
||Director, Japan Medical Laser Laboratory, Tokyo, Japan

Post herpetic neuralgia can be an extremely painful condition which in many cases proves resistant to all the accepted forms of treatment. It is frequently most severe in the elderly and may persist for years with no predictable course. This trial was designed as a double blind assessment of the efficacy of low level laser therapy in the relief of the pain of post herpetic neuralgia with patients acting as their own controls. Admission to the trial was limited to patients with established post herpetic neuralgia of at least six months duration and who had shown little or no response to conventional methods of treatment. Measurements of pain intensity and distribution were noted over a period of eight treatments in two groups of patients each of which received four consecutive laser treatments. The results demonstrate a significant reduction in both pain intensity and distribution following a course of low level laser therapy.

KEY WORDS Low level laser therapy Post herpetic neuralgia Pain relief

Post herpetic neuralgia can be an extremely debilitating condition. Its incidence increases with advancing age from 3 per 1000 population per year in the 20−49 age group rising sharply over the age of 60 years to 10 per 1000 population per year at 85 years or over.[1] Whilst uncommon in patients under the age of 40 years it occurs in more than one third of patients over 60 years of age who suffer an acute zoster attack. It is also unpredictable. Measurement of antibody response during the acute zoster phase does not predict the clinical outcome.[2] There is some evidence that the very early treatment of acute zoster may reduce the subsequent incidence of post herpetic neuralgia.[3] The condition usually remits spontaneously within 1−6 months but can persist for many years.

For more than a decade it has been accepted that surgical intervention in post herpetic neuralgia is unwarranted. Treatment protocols may vary from centre to centre but usually include oral medication, cutaneous stimulation, injection therapy, acupuncture and hypnotherapy. The need for conservative but intensive supportive treatment has been stressed.[4] In spite of all these measures some 15% of post herpetic neuralgia sufferers gain little or no relief. Anecdotal reports have suggested that low level laser therapy (LLLT) is effective in the relief of various types of neuralgia. This trial was designed as a double blind crossover assessment of the efficacy of LLLT in the treatment of the pain of well established and unrelieved post herpetic neuralgia.

Methods and Materials

The laser used for treatment was the Oh-Lase 3DI Gallium Aluminium Arsenide Diode Laser (Japan Medical Laser Laboratory) with a continuous wave 60 mW output at 830 nm in the contact mode of application. All procedures were carried out in accordance with DHSS guidelines for the use of Class IIIB lasers.[5] Two identical laser probe heads were used, one of which was adapted so as not to transmit the laser beam (dummy head). In all other respects the treatments were identical.

Patients admitted to the trial were taken from routine pain clinic referrals and had been suffering from post herpetic neuralgia for at least six months with little or no response to a wide range of treatments which included analgesics, nonsteroidal anti-inflammatory drugs, carbamazepine, clonazepam, various tricyclic anti-depressants, injection therapy both local and para-vertebral, transcutaneous nerve stimulation, acupuncture and hypnotherapy. The nature of the study was fully explained to each patient and their informed consent was obtained.

Twenty consecutive patients fulfilling the above criteria were randomly allocated by an independent agent for initial treatment by either the real or dummy probe head. Treatment sessions were performed twice weekly and lasted 20 min on each occasion. After four treatments the probe heads were exchanged and a further four treatments given. Neither the laser therapist nor the patient was aware of the identity of the probe heads. Thus two groups of patients were formed. Group A underwent initial treatment with LLLT for four sessions whilst Group B were initially treated as controls. All patients received eight identical treatments. Current medication was

Address correspondence to:
Dr. K. C. Moore, Department of Anaesthesia, Oldham Royal Infirmary, Union Street West, Oldham OL8 1DJ

continued unchanged throughout the period of the trial.

Prior to each treatment session measurements of pain severity and distribution were taken. Pain intensity was measured by patient self assessment on a linear analogue scale of 0–10. Pain distribution was mapped out over the affected area and measured by body surface perimetry using a universal goniometer (Duffield Medical). One week after the completion of treatment patients were reviewed and final measurements of pain intensity and distribution were taken. Further follow ups were arranged at intervals of six weeks.

Measured values for both groups of patients at the mid and end point of the trial were subjected to statistical analysis using a two tailed Student's t test at 99% level of confidence. Results greater than 3.3554 were of statistical significance.

The trial was authorized by the local Research and Ethical Committee.

Results

Of the 20 patients included in the trial 11 were male and 9 were female with a mean age of 69 years (Range: 55–82 years) and a mean duration of post herpetic neuralgia of 2½ years (Range: 6 months–8 years). All cases were unilateral and affected the thorax (9 cases), head and neck (5 cases), upper limb (4 cases) or abdomen (2 cases).

Table 1. Effect of LLLT in post herpetic neuralgia

	Pain Score (0–10)		Pain Distribution (%)	
	Group A (n=10)	Group B (n=10)	Group A (n=10)	Group B (n=10)
1	10	10	100	100
2	6.2	9.4	79	97
3	4.4	9.2	60	94
4	2.6	8.9	41	94
5	2.1	9.3	34	89
6	2.1	5.4	31	61
7	1.9	4.3	31	50
8	1.8	3.4	31	42
9	2	3.3	31	41

all values are means

Table 1 presents the measured values of pain intensity and pain distribution for the two groups of patients. Group A showed a marked reduction in pain score during LLLT of almost 80% compared with a reduction of less than 10% during the control treatments in Group B. End of trial pain scores were 2 in Group A and 3.3 in Group B following LLLT. Pain distribution values at midpoint of the trial showed Group A (LLLT) 34% and Group B (control) 89% of initial measurements. End of trial pain distribution values were 31% and 41% respectively.

Figures 1–4 present a graphic comparison of the recorded trial values as percentage changes in each estimation related to the initial pretrial levels. Figure 1 shows the values for Group A. Pain intensity fell rapidly during LLLT, plateauing out over the control phase. Pain distribution followed a similar but less pronounced trend finishing with a value some 10% higher. Figure 2 demonstrates the graphic results from Group B. During control treatment there was an improvement of approximately 10% in both pain intensity and distribution. The LLLT phase of treatment showed a similar reduction in pain severity and distribution to that achieved in Group A but plateauing out at levels some 10% higher. Figures 3 and 4 compare the relationship between pain intensity (Figure 3) and pain distribution (Figure 4) in the two groups of patients and demonstrate similar patterns of response to control and laser treatment.

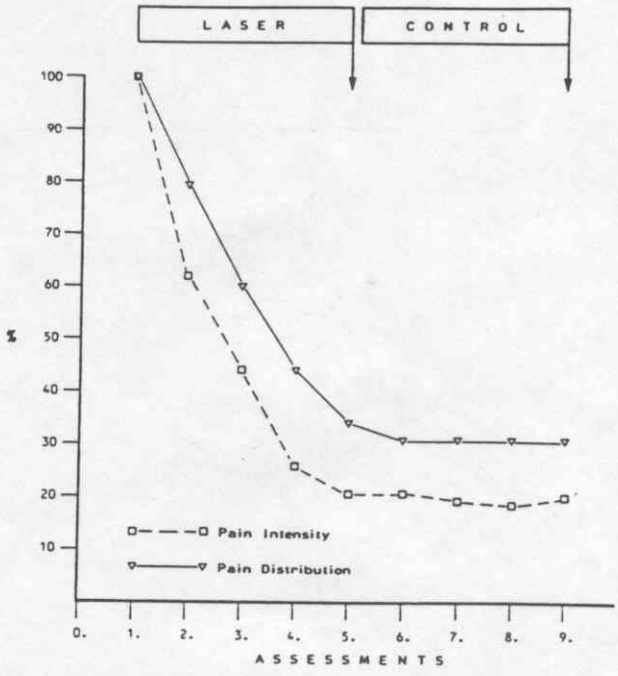

Figure 1. Effect of LLLT in post herpetic neuralgia. Pain intensity and distribution: Group A

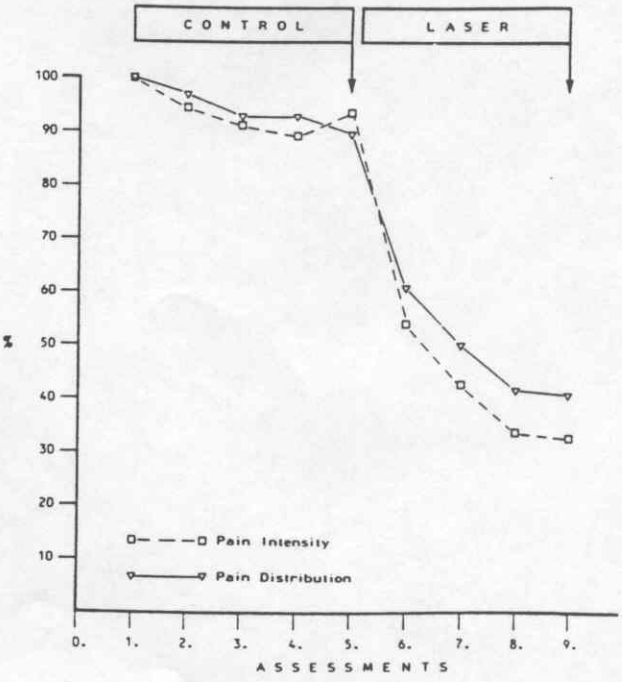

Figure 2. Effect of LLLT in post herpetic neuralgia. Pain intensity and distribution: Group B

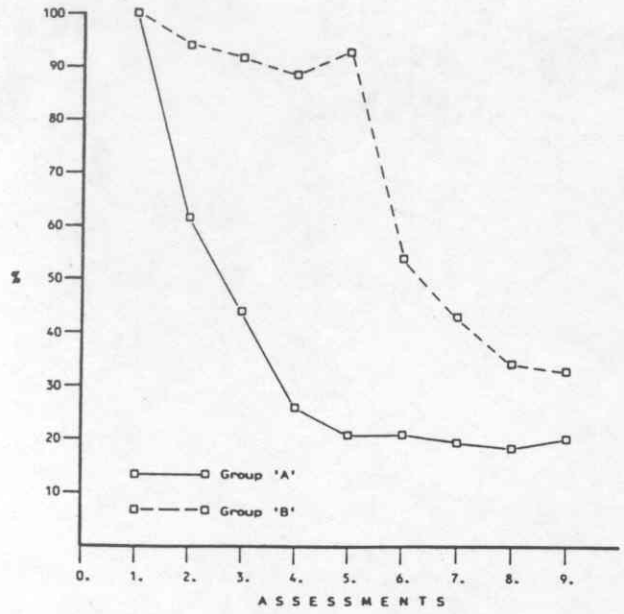

Figure 3. Effect of LLLT in post herpetic neuralgia. Pain intensity comparison

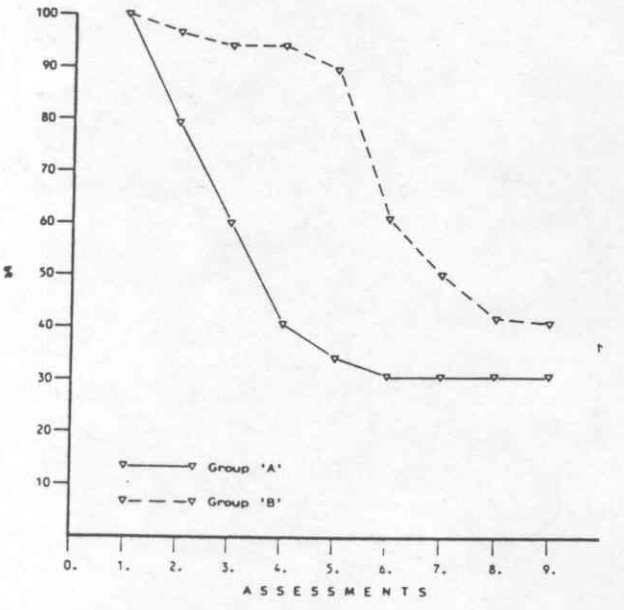

Figure 4: Effect of LLLT in post herpetic neuralgia. pain distribution comparison

Table 2 presents statistical analysis data for mid and end point trial values. Student's *t* test values in excess of 3.3554 were significant. The differences in mid trial values between Groups A and B for both pain intensity and distribution were statistically significant, whereas end trial differences for the same parameters were not significant.

At review, following completion of treatment, all medication was discontinued in 19 patients (95%). The remaining patient required continuing medication but in reduced dosage. Long term follow up to date has been limited to between 3 and 6 months. During this period 16 patients (80%) have maintained their improvement in pain levels and distribution, and 4 patients (20%) have had some recurrence of their post herpetic neuralgia. In 2 patients the pain returned to a score of 4 which they found an acceptable level not requiring the reintroduction of medication. The remaining 2 patients demonstrated a return to pain scores of 6 and 8, and in both cases were recommenced on their previous therapy. Further follow up of all cases will be continued.

Table 2. Effect of LLLT in post herpetic neuralgia

	Statistical Analysis				
	Group A	s.d.	Group B	s.d.	*t*
Pain Intensity					
mid point	2.1 ±	0.876	9.3 ±	0.675	20.588
end point	2.0 ±	1.183	3.3 ±	1.159	2.482
Pain Distribution					
mid point	34.3 ±	13.225	89.8 ±	3.521	12.823
end point	31.2 ±	11.631	41.5 ±	9.857	2.136

s.d. = standard deviation
t = Student's *t* test value

Discussion

The assessment of chronic pain is a difficult problem as it is subject to individual psychological and emotional influences. Patients with long standing pain frequently demonstrate symptoms of depression. In its most severe and unrelieved form post herpetic neuralgia can even induce suicidal tendencies. In spite of the many and varied forms of treatment available, some 15% of patients, particularly those in the elderly age group, have unrelieved pain. The patients in this trial fell into this category, 50% being over 70 years of age and 25% having suffered from the condition for more than 4 years.

Following a course of LLLT all the patients in the trial demonstrated a reduction in pain severity of between 40–95% (Mean: 74%) and a reduction in pain distribution of between 49–84% (Mean: 64%). Mid point differences between LLLT and control groups were of statistical significance. Whereas the initial 10% improvement in pain intensity and distribution in Group B during the control treatments may be ascribed to the placebo effect of attention and treatment, all subsequent improvement was as a direct result of the laser therapy. Limited follow up shows that the pain relief achieved has been maintained in the majority of patients with an associated improvement in the quality of life.

It is concluded that the Oh-Lase 3DI Gallium Aluminium Arsenide Diode laser offers a new method of effectively treating post herpetic neuralgia.

References

1. Hope-Simpson, R.E. (1985). The nature of herpes zoster: a long term study and a new hypothesis. *Proceedings of the Royal Society of Medicine* **58**, 9–20.
2. Sutherland, S. (1987). The biology of varicella-zoster virus. *Research and Clinical Forums* **2**, 17–22.
3. Huff, J.C. (1987). Oral acyclovir therapy of acute herpes zoster: a multicentre study. *Research and Clinical Forums* **2**, 37–43.
4. Crue, B.L. Jr. (1975). *Pain: Research and Treatment* Academic Press, London, pp. 289–292.
5. D.H.S.S. (1984). *Guidance on the Safe Use of Lasers in Medical Practice*. H.M.S.O., London.