

CAN LOW REACTIVE-LEVEL LASER THERAPY BE USED IN THE TREATMENT OF NEUROGENIC FACIAL PAIN? A DOUBLE-BLIND, PLACEBO CONTROLLED INVESTIGATION OF PATIENTS WITH TRIGEMINAL NEURALGIA

Arne Eckerdal and H Lehmann Bastian

*Department of Oral and Maxillofacial Surgery and Oral Medicine,
Odense University Hospital, Denmark*

Neurogenic facial pain has been one of the more difficult conditions to treat, but the introduction of laser therapy now permits a residual group of patients hitherto untreatable to achieve a life free from or with less pain. The present investigation was designed as a double-blind, placebo controlled study to determine whether low reactive-level laser therapy (LLLT) is effective for the treatment of trigeminal neuralgia. Two groups of patients (14 and 16) were treated with two probes. Neither the patients nor the dental surgeon were aware of which was the laser probe until the investigation had been completed. Each patient was treated weekly for five weeks. The results demonstrate that of 16 patients treated with the laser probe, 10 were free from pain after completing treatment and 2 had noticeably less pain, while in 4 there was little or no change. After a one year follow-up, 6 patients were still entirely free from pain. In the group treated with the placebo system, i.e. the non-laser probe, one was free from pain, 4 had less pain, and the remaining 9 patients had little or no recovery. After one year only one patient was still completely free from pain. The use of analgesics was recorded and the figures confirmed the fact that LLLT is effective in the treatment of trigeminal neuralgia. It is concluded that the present study clearly shows that LLLT treatment, given as described, is an effective method and an excellent supplement to conventional therapies used in the treatment of trigeminal neuralgia.

Key words: Low reactive-level laser therapy, trigeminal neuralgia, short and long term results, double-blind, placebo effect, controlled study

Introduction

Low reactive-level laser therapy (LLLT) is comparatively new in the Western world, although it has been used extensively in the former Eastern block counties in addition to the Far East. As a result, with some notable exceptions, there are very few reliable studies, despite the fact that there are innumerable case reports. Thus

it has been somewhat difficult to establish the necessary criteria for a prospective study.⁽¹⁾ The first report on LLLT of odontological patients in Denmark appeared in the Danish Dental Journal in 1988.⁽²⁾

The literature which is available gives little indication as to the efficacy of LLLT, nor does it provide guidelines as to the amount of LLLT necessary. Much has been written about the beneficial effects of LLLT in the treatment of pain; a number of authors have re-

Addressee for Correspondence:

Arne Eckerdal DDS DOS

Consultant, Department of Oral and Maxillofacial Surgery & Oral Medicine, Odense University Hospital, DK-5000 Odense, Denmark.

Manuscript received: September, 1996

Accepted for publication: November, 1996

ported positive effects of LLLT in cases of rheumatoid arthritis of the mandibular joint, trigeminal neuralgia and atypical facial pain.⁽³⁻⁹⁾ Others repudiate the suggestion that LLLT has any real effect as an analgesic;⁽¹⁰⁻¹²⁾ some authors maintain that any effect actually observed is due to the so-called placebo effect associated with being treated with 'a laser'.^(11,13,14) Accordingly, there is obviously an urgent need for well-planned placebo controlled studies in order to establish the value of LLLT. No side-effects of any consequence have been reported up to the present with over two decades of clinical reporting of LLLT, and therefore it may be argued that clinical studies can be carried out with impunity, provided all patients sign forms of informed consent and the studies meet the requirements of the particular institution's ethical committee.

The object of the present investigation was to determine whether LLLT with an 832 nm diode laser was effective, and if so, what long-term results can be expected.

Materials and Methods

Patients

The patient population was assembled prospectively from a series of consecutive patients suffering from trigeminal neuralgia referred to the Department of Oral and Maxillofacial Surgery and Oral Medicine of the Odense University Hospital. The final population consisted of 32 patients. The patient's case history was recorded and a note made of any possible allergy, as well as the patient's drug consumption, paying particular attention to analgesics. Both a clinical and X-ray examination were carried out in order to eliminate any possible pathological process in the area of the oral cavity. All of the patients who enrolled in the investigation gave their informed consent; further, they were given written information covering all aspects of the study. Patients who had been subjected to transection or excision of the nerve, cryotherapy or alcohol blockade at an earlier date were excluded from the investigation.

Assignment to treatment group

The initial examination consisted of palpation and recording of the trigger points, as well as particularly painful points. Trigger points are defined in this context as sites on the face of neck which triggered pain along the anatomical path of the affected branch of the trigeminal nerve, following pressure on the point of interest. These points were marked on a standard drawing on the patient's chart, below which there was space to insert the date of laser treatment as well as the amount of LLLT delivered. The patient thereafter selected a card at random, which decided whether they

were to be allotted to group A or group B. Probes A and B, for use in groups A and B respectively, had been supplied by the manufacturers, one being a dummy probe to assess the placebo effect, and the other an active probe delivering an output power of 31 mW. In every other respect, such as audible and visible emission signals, the probes were identical. Only the laser company was aware which probe was active, and so neither the dental surgeon nor the patient was aware which group was receiving real laser therapy and which group was the placebo.

Record-keeping

At the end of the first session, each patient indicated the intensity of their pain using a slightly modified Visual Analogue Scale (VAS) as suggested by Huskisson.⁽¹⁵⁾ Treatment was given once a week for five weeks. Each trigger point was given treatment comprising 2 J/point, and the number of trigger points varied from one to five. The patients gave a subjective evaluation of the pain intensity at each visit. A standard investigational form was filled in at each treatment session showing the results of the physical examination. Treatment with the probe was given at all the trigger points and painful points, with an energy density corresponding to 9.2 J/cm². The patients were provided with record cards on which they recorded their consumption of analgesics. The patients were recalled 1 year after the final session. Pain scoring was carried out at these times.

If the patient developed recurrence of the pain, then the treatment was considered unsuccessful and the patient was transferred to another treatment. The study took place over a four year period during which the two groups of patients who had been subjected to laser and to placebo treatment comprised a total of 32; 14 in group A having an average age of 65 years (4 males, 10 females); and 18 in Group B (8 males, 10 females) with an average age of 62 years (Table 1). The average age for the whole population was 63.5 years. Statistical analysis showed that both groups were comparable (Mann-Whitney test).

Table 1: Distribution of trigeminal neuralgia patients, in Groups A (placebo) and B (LLLT), according to sex and age. The groups were assessed to be of similar composition (Mann-Whitney test).

| Group | Total No. | Male | Female | Age (M) | Age (F) |
|---------|-----------|------|--------|-----------------|-----------------|
| Group A | 14 | 4 | 10 | 67.0 (53-91) | 64.5 (32-92) |
| Group B | 16 | 7 | 9 | 63.5 (42-76) | 61.0 (42-92) |

Table 2: Results of treatment of trigeminal neuralgia in Group A (Placebo) at the end of the treatment (five weeks) and at one year follow-up (n=14).

| Sampling point | Successful | Improved | No change |
|------------------|------------|----------|-----------|
| at end of trial | 1 | 4 | 9 |
| 1 year follow-up | 1 | 0 | 13 |

Successful = totally pain-free. Improved = minimum of two point improvement on Huskisson VAS. No change = less than 2 points on VAS

Laser system

A p-laser type CBS-Master III, manufactured by C.B. Médico A/S, Vaerlose, Denmark, was used; this emits light in at 832 nm in the near infrared, and is a GaAlAs laser with an output power of 32 mW in continuous wave. This system is classified as a class 3B laser.

The two probes were returned to the manufacturers at the conclusion of the study. They informed us that probe A was inactive delivering 0 mW whereas probe B was active, delivering 31 mW (C.B. Medico A/S, Vaerlose, Denmark). Neither probe had an aiming beam and as 830 nm is invisible to the human eye, the inactive probe could not be identified from the active probe in any way.

Analgesic consumption

The analgesic record cards were collected from the patients after completion of the investigation. The consumption of analgesics could then be analyzed by employing a pain index in which the various types of drugs were assigned a value of from one to ten. Over-the-counter drugs (non-prescription) were given a value of from 0.5 to 1.0, moderate analgesics were assigned 3. These included non-steroidal anti-inflammatory drugs, such as ibuprofen and similar types. Carbamazepine and oxcarbamazepine were assigned values of 4 to 5, while the values of opiate-based drugs ranged from 6 to 10. These values were recorded for each patient for the first 30 days. Each group (groups A and B) was then summarized on a daily basis, thus giving a total average analgesic consumption score for each day which was then divided by the number of patients in the group. These data were then illustrated graphically.

The criteria employed for success were firstly a reduction in the pain score on Huskisson's VAS of at least two points and secondly no increase in the initial dose of medication or the use of more powerful analgesics.

Table 3 Results of treatment of trigeminal neuralgia in Group B (real LLLT) at the end of the treatment (five weeks) and at one year follow-up (n=16).

| Sampling point | Successful | Improved | No change |
|---------------------|------------|----------|-----------|
| At end of trial | 10 | 2 | 4 |
| At 1 year follow-up | 6 | 0 | 10 |

Successful = totally pain-free. Improved = minimum of two point improvement on Huskisson VAS. No change = less than 2 points on VAS

Results

Group A.

This group comprised a total of 14 patients. At five weeks five patients reported some degree of effect of the treatment of whom one was completely pain free. The remaining nine were unable to report any benefit from the treatment. One year after the treatment had been completed, one patient was still pain free, with the remaining 13 reporting little or no improvement from their preirradiation findings. (Table 2).

Group B

This group finally totalled 16 patients, in as much as two of the original group were drop-outs. The first, an elderly female, did not register pain on the VAS. The second patient, a male, had such diffuse symptoms, all of which varied in type and intensity at each session, that there were serious doubts as to whether or not he suffered from facial pain or whether he was in actual fact suffering from psychogenic pain associated with a psychological disorder.

At the completion of the course of treatment 12 patients reported successful treatment, of whom 10 were totally pain-free. The remaining four stated that there was little or no improvement. One year later, six of the patients stated that they were still entirely free from pain with the remainder reporting little or no improvement from their preirradiation findings (Table 3).

There was no statistical difference in the consumption of analgesics in group A between the quantity used before the investigation and that used after the study had been completed. In group B the use of analgesics diminished considerably paralleling the clinical observations (Figure 1).

Discussion

The present investigation, in contrast to earlier studies,⁽¹¹⁾ clearly demonstrates that a course of treatment consisting of five sessions of LLLT can relieve pain in patients suffering from trigeminal neuralgia. Figure 1 shows that patients in group B had a considerably reduced consumption of analgesics, as compared to

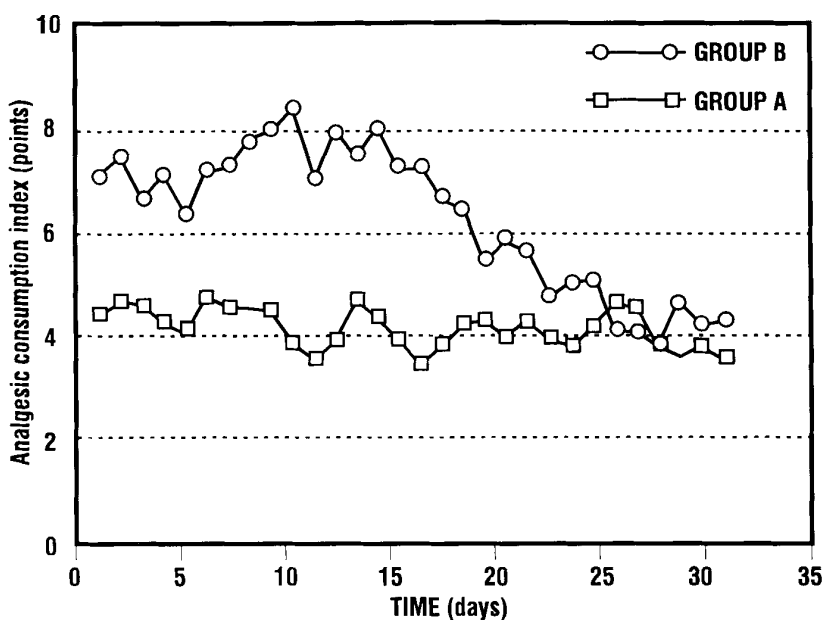


Figure 1 Daily analgesic consumption index over 30 days comparing the LLLT treated group (Group B) with the sham irradiated placebo group (Group A). The initial average analgesic consumption level for Group B was much higher than for Group A, but had by the end of the trial dropped to just above half the initial value. In Group A, although the initial consumption was much lower than Group B, by the end of the trial there was little change in the consumption of analgesics in the placebo patients.

patients in group A. Thus, our study shows that there is an alternative and/or supplementary treatment to that used at present, which in many cases consists of high doses of drugs such as carbamazepine or oxcarbazepine.

It is essential that the dental surgeon is aware of the various types of treatment that can be given in cases of trigeminal neuralgia, in order that the patient can be offered optimal treatment. Newer methods of treatment are frequently the subject of criticism by the established system. However, there can be little doubt after the present investigation that LLLT has a definite place in the treatment of trigeminal neuralgia, especially in patients with severe side-effects following conventional drugs, or fail to respond well to them.

Standard guidelines should always be employed when treating facial pain. These guidelines should include the method to be employed in finding the trigger zone or spots.⁽¹⁾ It is vital that the trigger zones or spots be found when giving LLLT, otherwise the treatment is likely to prove ineffective. This aspect of LLLT appears to have been overlooked in previous studies.⁽¹¹⁾ If these zones are not found and laser is given by random application dictated by intuition alone, then it is certain that the treatment will be a failure.

Detailed study of the trigger points showed that involvement of the 2nd branch of the trigeminal nerve seems to be of importance in order to obtain good

results. This may be associated with the anatomical structures, where the second branch is considerably closer to the ganglion than the other two. Furthermore, detailed analysis of the pain intensity (VAS) showed that when effective, real LLLT in the great majority of patients produced either complete freedom from pain, or reduced the intensity by at least four points. Our criterion for successful treatment, namely a reduction of at least two points on the VAS, could have been changed to four points without any significant changes in the statistical results.

There was a considerable difference in the initial use of analgesics between the two groups. Group B demonstrated approximately twice the consumption of analgesics drugs as group A; this would indicate that the intensity of pain in group B was considerably higher than that in group A. At the end of the treatment there was no change in the consumption of analgesics in group A, whereas in group B, the consumption had dropped to a level comparable with that of group A. In other words drug consumption in the real LLLT group was halved at the end of the study compared to the initial levels. The reduction in drug consumption, in itself, proves that LLLT is effective. In this context it is interesting to note that the drug consumption rose during the two days following the second treatment and thereafter dropped considerably in Group B. This phenomenon was also seen in Group A (placebo group),

although the increase was followed by a drop only to the earlier level of consumption.

One possible criticism of the investigation is that the investigator would fairly rapidly realize which of the probes delivered LLLT because of the results, or lack of them, reported by the patients. However, this criticism can be leveled against almost any investigator, not to form an opinion as to which group is receiving the active treatment. This fact will have little or no effect on the results reached in the investigation providing the investigator does not consciously or subconsciously attempt to influence the patient.⁽¹⁴⁾

Another obvious fault is the comparatively small patient population, but it is a fairly esoteric complaint and we wanted to get our preliminary results down on paper.

The treatment of trigeminal neuralgia is, at least in our opinion, team work. Many patients can be helped quite effectively using pharmacotherapy, but there will always remain a group of patients who are plagued to such an extent by pain that they are completely incapacitated; part of this group can now be helped by LLLT, so that they can achieve a tolerable life-style. The team necessary when presented with patients with facial pain must include a neurologist, an ENT surgeon, a neurosurgeon and a dental surgeon. If such a team can work across conventional specialities, then the possibility exists of helping many patients whose daily life has consisted of enduring excruciating pain and whose overall quality of life (QOL) is extremely poor. LLLT, in combination with a reduced dosage of drugs, offers improvement in QOL to a considerable number of this latter group of patients.

Although the precise mode of action of LLLT on pain attenuation is not entirely understood at present, some recent reports have indicated the manner in which LLLT effects the living cell, the latest suggesting that laser irradiation selectively inhibits nociceptive neuronal activities.^(3-9,16,17) Much work is therefore required before this aspect of LLLT can be elucidated.

Conclusions

The present investigation has clearly shown that LLLT, given as described, is an effective method and an excellent supplement to the conventional therapies used in the treatment of trigeminal neuralgia. Further, detailed study has shown that the second branch of the trigeminal nerve must be involved before any effect can be expected, and that in the great majority of cases where

LLLT is effective, the patients become completely free from pain.

References

- 1: Eckerdal A (1994): Kliniske erfaringer fra et 5-års ikkekontrolleret studie af low power laserbehandling af periorale neuropatier. *Danish Dental Journal*, 18: 526-8.
- 2: Bastian HL: (1988): Laserlys og dets anvendelse. *Danish Dental Journal*, 18: 728-31
- 3: Goldman JA, Chiapella J, Casey H, Bass N, Graham J, McClatchey W. (1980): Laser therapy of rheumatoid arthritis. *Lasers in Surgery and Medicine*, 1: 93-101.
- 4: Hansson TL (1989): Infrared laser in the treatment of cranio-mandibular disorders, arthrogenous pain. *Journal of Prosthetic Dentistry*, 61: 614-6.
- 5: Bezuur NJ, Habets L and Hansson T (1988): The effect of therapeutic laser treatment in patients with craniomandibular disorders. *Journal of Craniomandibular Disorders*, 2: 83-6
- 6: Popov B (1986): Treatment of trigeminal neuralgia with local laser irradiation and laserpuncture. *Stomatologija Bulgaria*, 68: 25-9.
- 7: Håkansson A, Wiklander C (1986): Laserbehandling i öppenvård. *Sjukgymnasten*, 2: 12-3.
- 8: Honmura A, Yanase M, Obata J and Haruki E (1993): Analgesic effect of GaAlAs diode laser irradiation on hyperalgesia in Carrageen-induced inflammation. *Lasers in Surgery and Medicine*, 13: 463-69.
- 9: Walker J (1983): Relief from chronic pain by low power laser irradiation. *Neuroscience Letters*, 43: 339-44.
- 10: Fernando S, Hill CM and Walker R (1993): A randomised double blind comparative study of low level laser therapy following surgical extraction of lower third molar teeth. *British Journal of Oral and Maxillofacial Surgery*, 31: 170-2.
- 11: Hansen HJ, Thorøe V (1990): Low power laser biostimulation of chronic orofacial pain. A double-blind placebo controlled cross-over study in 40 patients. *Pain*, 43: 169-79.
- 12: Jensen H, Harreby M, Kjær J (1987): Infrarød laser effekt med smertende knætrøse? *Ugeskrift Læger*, 149: 3104-6.
- 13: Peck C, Coleman G (1991): Implications of placebo theory for clinical research and practice in pain management. *Theoretical Medicine*, 12: 247-70.
- 14: Scovlund E (1991): Placebo effects and controlled clinical trials. *Tidskrift Norske Lægeforening*, 111: 2728-31.
- 15: Huskisson EC (1974): Measurement of pain. *Lancet*, 1974: 1127-31.
- 16: Tsuchiya K, Kawatani M., Takehige C & Matsumoto I (1994): Laser irradiation abates neuronal responses to nociceptive stimulation of rat-paw skin. *Brain Research Bulletin*, 31: 369-374.
- 17: Tsuchiya K, Kawatani M, Takeshige C, Sato T and Matsumoto I (1993): Diode laser irradiation selectively diminishes slow component of axonal volleys to dorsal roots from the saphenous nerve in the rat. *Neuroscience Letters*, 161: 65-68.