Low level laser for the stimulation of acupoints for smoking cessation: a double blind, placebo controlled randomised trial and semi structured interviews

By: Catherine M. Kerr, Paul B. Lowe & Neil I. Spielholz

Keywords: Acupoint stimulation, laser, smoking, nicotine, addiction.

Abstract

Aim: to determine whether the application of laser acupoint stimulation to previously reported effective ear and body acupuncture points was successful in reducing the physical symptoms of withdrawal, so promoting a complete cessation of smoking. **Design:** The method used was that of a double blind, randomised controlled trial and semi-structured interviews. Adult volunteers (n=415) were recruited following a television appeal. After initial screening and application of inclusion/exclusion criteria the volunteers (n=387) were randomly allocated to either of the treatment groups A or B or C. **Intervention:** Three laser therapy treatments on days 1, 3 and 7 of the programme and one sham treatment on day 14 (Group A) or 4 laser treatments carried out on days 1, 3, 7 and 14 (Group B) or Group C with four sham treatments on days 1, 3, 7 and 14. Sham treatments used an inactive probe identical in appearance to active probe. **Findings:** Groups A and Group B participants achieved a higher rate of non smoking than Group C. Of the two groups, four treatments (Group B) was more effective than the three treatments (Group A). The differences in the non smoking behaviors of all three groups were statistically significant. Subjective data reported a lessening of withdrawal symptoms after laser treatment. **Conclusions:** Laser acupoint stimulation can assist in smoking cessation by reducing the physical symptoms of withdrawal.

Introduction

From July 2007 all enclosed public places and workplaces in England became smoke free. The Government claim that this will ensure a healthier environment so that everyone can socialise, relax, travel, shop and work free from secondhand smoke (The Health Act 2006). Secondhand smoke is the smoke that is given off by the burning end of a cigarette, cigar or pipe and the smoke that is exhaled by the smoker. Tobacco smoke contains at least 40 chemicals which are known to cause cancer and the long term effects of exposure include increased risk of heart disease, lung cancer, asthma and other respiratory diseases. Smoking is not only harmful but will now no longer be seen as an acceptable social activity. As a consequence it is expected that many people will use this opportunity to cease smoking permanently.

Nicotine is the stimulant found in tobacco whose physiological effects include an increase in concentration, relief of tension and fatigue. It is these effects that smokers desire. Consequently removal of the drug nicotine involves physical detoxification. During detoxification receptor sites once blocked by nicotine become freed, but the natural substance endorphin which occupied the cell receptor sites prior to use of nicotine is missing. Endorphins normally inhibit the transmission of pain and without them physical symptoms develop that include nausea, headache, insomnia, fatigue, drowsiness, irritability and inability to concentrate, all of which are recognised as signs of withdrawal (BMA 2004). It may take some time for endorphin occupation of the receptor sites to reach a significant level and until then withdrawal symptoms will be felt. In order to promote the cessation of smoking there has to be a way of reducing and eradicating these symptoms and that in turn means using a therapy that stimulates endorphin production within the body (Marovino 1994, BMA 2004).

Acupuncture has been used for the treatment of nicotine addiction for almost four decades (Wen and Cheung 1973, Wong and Fung 1991). It involves the excitation of specific acupoint sites on the body in order to induce the physiological effect of imparting a responsiveness in otherwise unresponsive tissue thus stimulating the production of endorphins and eliminating the condition of long term stress experienced by deprivation from nicotine (Cheung 1986, Strauss 1987). A more recent form of acupoint stimulation involves the use of lasers which use low level radiation to stimulate the acupoints using previously reported effective ear and body acupuncture points (Kerr at al 2000).

This study aimed to determine whether the application of low level laser radiation directed to stimulate specific acupoints on the body can bring about cessation of smoking by reducing the physiological symptoms of withdrawal and tests the hypothesis that:

A significantly higher proportion of subjects who receive low level laser radiation to stimulate selected acupoints on the ear and body will achieve smoking cessation than do subjects who receive sham laser to the same acupoints

Method and materials

Recruitment of subjects

Subjects were recruited for this study following the appearance of the researchers on a current affairs programme on local television. Interested parties were asked to contact the researchers via telephone, providing contact details and expressing a willingness to participate fully in the study. No financial remuneration or other incentives were to be offered to suitable participants The primary inclusion criterion for this study was that they were smokers who wished to give up smoking and that they had not received laser therapy before. Potential participants (n=415) were invited to attend for interview and a routine screening for possible participation in the trial. Each participant underwent initial health screening prior to treatment which included past medical history, current health status, medication and smoking history. The reasons for wanting to stop were also discussed with each subject as well as any previous attempts at smoking cessation. Physiological measurements of pulse, blood pressure, peak expiratory flow rate and body weight were recorded in order to identify any disorder that would be contraindicated and establish a baseline for further comparison. All this data was documented on an especially designed data sheet. The researchers had established a set of exclusion criteria and these were pregnancy, uncontrolled ischaemic heart disease, asthma, unstable diabetes mellitus and unstable epilepsy, Persons under 16 years of age were excluded because of their minor status.

Of the 415 subjects who initially expressed interest in participating in the study, 28 were excluded on the basis of the exclusion criteria set by the researchers and 47 either withdrew part way through the study or did not attend for any of the treatments. A total of 340 subjects therefore completed the treatment stage of the study. The age range of the subjects was 19 to 68 years of age. Fifty six percent were male (n=192) and the remaining 44 percent (n=148) female. All the subjects had been smoking from as long as one year to a maximum of fifty two years. The number of cigarettes smoked varied from a minimum of five per day to a maximum of sixty. All participants were given full information concerning the procedure of the study and asked to sign a consent form following successful pre-study screening. Subjects were randomly allocated to treatment groups A, B or C. Randomisation was achieved by firstly allocating each individual an ordinal number at the screening visit then, using a random number table, selecting and allocating them sequentially to each of the study groups. The choice of two treatment groups had emerged following a pilot study in which 23 volunteers had participated (Kerr et al 2000). In the pilot study only a course of three laser treatments had been administered. At the end of this study period 48% (n=11) of the participants had expressed the need for an additional laser treatment. It was felt that this was worthy of inclusion in the main study, which had a large population, so as to compare outcomes from both treatment groups against themselves and the control and to test for possible statistical significance. Neither the researchers nor the participants knew which treatment had been administered until the end of the study. At the end of that time the persons who had been part of the control group were informed that they had not received the intervention and were offered the laser treatment.

For ethical reasons the study design and protocol was reviewed by Middlesex University ethics committee and ethical approval to continue was granted. All the participants signed a consent form.

Procedure

Subjects attended for four sessions of treatment followed by follow-up sessions at three and six months post-treatment, and replied to a questionnaire at 18 months. Prior to each treatment physiological measurements were recorded to detect any changes and records kept. Subjective data concerning current smoking status and feelings of well being or otherwise were also recorded. The treatments were carried out in a suitable clinic room and timetabled so that the participants never encountered each other, thus ensuring that there was no opportunity to confer or develop any form of support network. For the same reason the researchers did not offer information or advice concerning smoking cessation. The aim of the study was to investigate whether stimulation of acupoints using laser only could bring about a cessation in smoking by modifying the physiological functions that support addiction and it was felt that this would only be seen if the lone intervention was observed.

Subjects in treatment group (Group A) received laser treatment on days 1, 3 and 7 of the study using the active probe, and a fourth treatment on day 14 using the sham or inactive probe. Those in treatment group (Group B) received treatment on days 1, 3, 7 and on day 14 using the active probe. In Group C treatments were performed on days 1, 3, 7 and 14 using the sham probe. All treatments were carried out under blinded conditions.

For blinding, the researchers were given two probes named A and B. The probes were identical in appearance and had been preset to either active or inactive. The inactive probe was set by an independent technician from within the University while the company supplying the laser equipment set the active probe. The active probe emitted no light, did not vibrate, get hot, or give off a sound or any other indication that it was different from

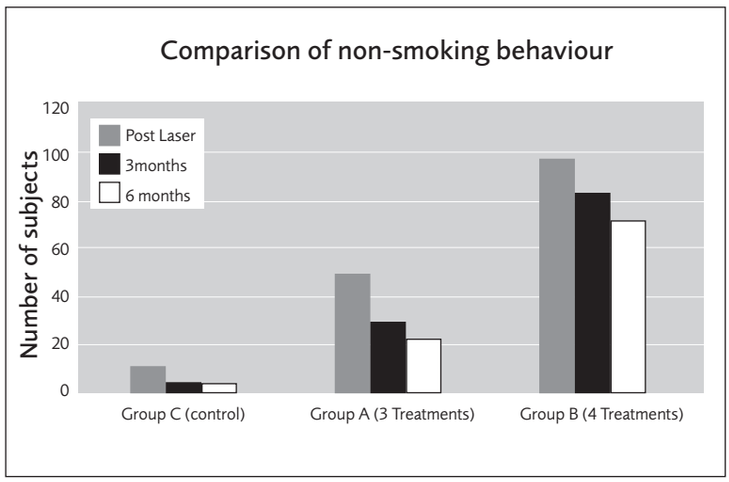

Table 1: Comparison of non-smoking behaviour between groups C, A and B immediately post laser to 6 months.

the inactive probe. The researchers were not present when the probes were set nor were they aware which probe was active. That information was retained by Omega Laser Systems London UK.

Intervention

Treatment consisted of irradiation using a single diode laser (Omega Laser Systems, London) and the following irradiation parameters: power output: 50mW; wavelength: 820nm; pulse repetition rate: 20Hz; radiant exposure: 24Jcm^{-2}. The acupoints used for treatment were on the ear (Shenmen, Lung, Adrenal, and Addiction points), and on the wrist/hand (Shenmen HE-7, Daling P-7 and Hegu L.I.-4).

Each point was in contact with the laser tip for the duration of one minute. Both the right and left sides of the body were used, making the total treatment time 14 minutes on each visit. If the subject had any history of heart disease (n=10), then the ear acupoint Shenmen was omitted. All points were treated in all three groups, using the active irradiation probe in Groups A for three out of four treatments, for all treatments in Group B and the inactive probe for all treatments in Group C. Point location was determined according to a chart supplied by the laser company and the practitioners practised locating the points together to ensure consistency between treatments. White et al (2001) argue that this is not the most accurate way of finding the exact spot but it must be remembered that each individual is different anatomically and exactness is not possible. Skill in detecting the acupoints had been acquired during the pilot study but the researchers were also aware that acupoint stimulation using lasers delivers a more diffuse stimulation because of what has been described as backscattering within the skin around a superficial point, so a little inaccuracy in point determination would have no effect (Anderson et al 1989).

Outcome measurements

The primary outcome measure for the current study was a complete cessation of tobacco smoking. This included not using tobacco in any other form such as snuff or chewing, nor using any type of nicotine replacement therapy (NRT). The participants were categorised as C*eased Smoking* or *Still* S*moking*. Follow up assessments were timetabled for three and six months and a questionnaire designed for 18 months after completion of treatment to assess any change in smoking behaviour in the intervening period. Changes were established from the verbal declaration of the participants. No attempt to check the validity of their statements using other scientific testing was made as this had not been written into the initial research protocol and therefore was not consented to. This was a study to which the subjects had volunteered cooperation and to which concealment of the truth brought no benefit, so their word was accepted and formed part of the findings.

In addition, physiological measurements of heart rate, blood pressure, peak expiratory flow rate and body weight which had been checked prior to each treatment session were rechecked at the end of three months and six months in order to detect any longer term changes to the baseline measurements. Subjective data concerning current smoking status and feelings of well being or otherwise were accumulated.

Data analysis

Data were compared between groups and displayed descriptively to show differences. Statistical significance of differences in *Ceased Smoking* and *Still Smoking* groups at the end of each time period was estimated. Subjective data were analysed and arranged into themes.

Results

Objective data findings from randomised controlled trial

Three hundred and eighty seven persons were initially accepted on to the study. At the start of the treatment time 6% (n=23) of persons did not attend for the treatment which had been scheduled after the initial screening and acceptance. A further 7% (n=24) withdrew after receiving either one or two treatments. The remaining 87% (n=340) went on to complete their respective treatment schedule. The number of participants in each group was now Group A (3 laser and 1 sham treatments) 121, Group B (4 laser treatments) 130, Group C (4 sham treatments) 89.

At the end of the three treatments the following findings were seen. Twelve persons from Group C had *Ceased Smoking* compared to 50 from Group A, and 97 from Group B. On comparing the two treatment

protocols A and B, those who had C*eased Smoking* in Group B showed an increase of 47 persons over group A. Both sets of findings show an improvement in their C*eased Smoking* patterns when compared with those seen in the Group C.

At the end of three months, the numbers of persons who remained as *Ceased Smoking* was five from Group C (a decrease of 58% on the previous reading), 30 from Group A (a decrease of 40% [n=20]), and 83 persons from Group B (a decrease of 15% [n=14].

At the end of six months, , the numbers of persons who remained as *Ceased Smoking* was five from Group C (no change from the earlier findings at three months), 23 from Group A (a decrease of 23% (n=7) on the previous reading) and 72 from Group B (a decrease of 13% [n=11]).

On comparing the *Ceased Smoking* behaviours of persons in Groups A and B it was obvious that the number who remained as ceased smoking was greater for treatment group B (four treatments) than for Group A (three treatments). There was a larger number of persons of C*eased Smoking* status in both groups when compared to Group C (control).

At the end of 18 months all the participants were sent a questionnaire requesting information concerning their current smoking behaviour. Of the 340 persons originally seen and treated, only 12% (n=40) persons replied. Eighty percent of the respondents (n=32) remained as having *Ceased Smoking*. Ten of the 32 had belonged to Group A, 22 to Group B and the remaining 8 to Group C. There was insufficient data for statistical analysis.

All physiological measures remained within normal limits during the trial.

Time	Degrees of freedom	Chi square value	*P* value
Post laser	2	87.2	≤0.001
3 months	2	87.2	≤0.001
6 months	2	72.8	≤0.001
18 months	2	insufficient data	

Table 2: **Summary of statistical findings for Groups A, B and C over time (the distribution is significant in all groups.)**

After six months with all the Dropouts replaced as *Still Smoking*
DF; 2, Chi square = 88.6 p value ≤0.001

Table 3: **Findings following first ITT analysis.**

After 6 months with all the Dropouts replaced as *Ceased Smoking*
Degrees of freedom; 2, Chi square = 34.8 p value ≤0.001

Table 4: **Findings following a second ITT analysis.**

Statistical analysis

Using Chi-squared on all the above sets of data showed the differences in *Ceased Smoking* and *Still Smoking* behaviours between the groups to be significant.

Forty seven subjects who had originally met the inclusion criteria and been randomised into the 3 groups, did not complete the requisite treatment protocols. An ITT analysis was then performed using the 6-month follow-up data that included all the treated population (n =340) plus those who had not completed the full treatment protocol (*Dropouts*) and placing them in the S*till Smoking* category (n =387). The results were statistically significant

However the largest number of persons failing to complete the treatment (n = 38) occurred from within the control Group C, reducing its participant number to 89. This was a considerable reduction in comparison to the remaining participant numbers in Group A (n = 117) and Group B (n = 125) and there was a concern that this could be having the pseudo effect of enhancing the effectiveness of the laser acupoint stimulation treatment. Steiner and Geddes (2001) suggest that one way of dealing with missing data is to assume the worst case scenario and accept that the significant outcome that was achieved was the result of so many persons leaving the control group. Applied to this study, their suggestion would be to record all the dropouts in Control Group C as having been successful in ceasing smoking. If the result on recalculating the ITT was then still significant then the significance would not be due to the dropouts in Group C but is more likely to be due to the effectiveness of the treatment. In order to test this reasoning for this study all the *Dropouts* from the control Group C were replaced as *Ceased Smoking* and the ITT recalculated. The statistical outcome remains significant and continues to lend support to the efficacy of the treatment.

Physical effects
Irritability 30%
Tiredness 12%
Calmness 12%
Anxiety 9%
Lack of cravings19%
Unpleasant taste when smoking 8%
Headaches 3%
Lack of concentration 38%
Increased appetite 11%

Table 5: Physical effects experienced by subjects during the study.

Subjective data obtained from the RCT

In addition to the objective data, just over half of participants to the study (n=184) described other effects which only they were aware of. At the follow up interviews many effects were identified.

The most frequently mentioned were linked together to form the following major themes:

- the lack of cravings
- feelings of tiredness and anxiety
- irritability and lack of concentration
- headaches and increased appetite

Discussion

The results from this double blind placebo controlled trial did support the hypothesis that low level laser acupoint stimulation was significantly more effective than the placebo in bringing about a cessation in smoking behaviour and that the effectiveness continued up to six months. These can be summarised as follows:

First, both three and four low-intensity laser treatments, applied to specific ear and body acupoints as described, resulted in significantly higher proportions of individuals who ceased smoking for up to six months than did those exposed to placebo laser therapy.

Second, four laser treatments were associated with significantly higher proportions of individuals who ceased smoking for up to six months than did three laser treatments.

Third, the relative risk for stopping smoking for at least six months after these treatments were 3.4 for Group A versus Group C, 9.8 for Group B versus Group C, and 2.9 for Group B versus Group A. Thus, both laser therapy groups were associated with higher likelihoods of smoking cessation for up to at least six months than placebo, and four laser treatments were associated with an almost three-fold increase in smoking cessation compared to three laser treatments.

Subjective data from some subjects in this study suggested that laser acupoint stimulation took away their cravings. The craving experienced by all addicts is what mostly drives them to seek further doses of the drug. Without cravings there is no need to take the drug, hence more subjects in Groups A and B ceased smoking; they no longer desired a cigarette. Other participants in the study claimed that it was the feeling of calmness and reduced anxiety that made it possible for them to stop smoking. Smoking is a stimulant causing the body to produce more epinephrine and norepinephrine both of which accelerate cellular energy utilisation and mobilise energy reserves (Martini and Bartholomew 2003). The sensation to the smoker is that of increased awareness and faster heart rate and breathing. Laser therapy appears to raise the level of endorphin, a natural opioid (Han 1982, Strauss 1987, Karavis 1997), to the point where a sense of warmth and well being was experienced. Different physiological responses occur in all persons so it is possible that this subgroup may have produced more endorphins than others and so had an enhanced feeling of well being which would have promoted sleep and rest and contributed to the sense of well being that they remarked upon. This pleasant state encouraged abstinence from tobacco.

Some of the group claimed to feel irritable and unable to concentrate although they experienced no cravings. Irritability is a recognised symptom of withdrawal and it is possible that these persons were not building up their own endorphin levels as quickly as others from within the groups. These persons would most probably have benefited from further laser treatment. If this could not be achieved then it seems highly likely that they would revert to smoking and this could go some way to explaining why many subjects within both treatment groups were not successful; they had simply not had enough laser treatment.

Statistical analysis between the treatment groups showed a significant difference between those who had had either of the laser treatments and the control. This lent further support to the theory for a physiological rebalancing of endorphins within the body induced by the stimulation of the acupoints. However it seems that the speed at which this rebalancing is achieved is different in each person and some may require more treatments while others need fewer. The significant difference in smoking cessation between Groups A and B would appear to support this.

A small number of subjects (8%) referred to the unpleasant taste of cigarettes when starting to

smoke again after several weeks of non smoking. There was also reference to headaches (3%) but these were not well described and it was difficult make judgments about whether they were of importance to this study or just coincidence. Some persons referred to eating more than usual (11%) but none of the group had increased in weight during the six months when they were most closely monitored. This was verified by regular weighings undertaken at the beginning of the study and at intervals of three and six months.

Conclusion

The results that emerged from the data indicated that acupoint stimulation using lasers does indeed modify the physical symptoms of withdrawal and make it possible for motivated persons to succeed in overcoming habitual smoking of tobacco, and this was further supported by the subjective comments made by the participants themselves, especially during the treatment phases and at the follow ups at three and six months. It seems that therapy involving acupoint stimulation is best given as a course of several treatments on at least four and possibly more occasions. Further studies would be needed to determine the optimum number. With regards to the RCT we feel that further studies such as this one are required to strengthen our findings and our reservations are based mostly upon the quality of the participants. Although large in number it was that of a self-selecting sample and this casts doubt on how generalisable the outcomes of the study may be to the general population.

Acknowledgements

We would like to thank the following persons who gave their time freely to assist us with the collecting of the data throughout this study: Arthur Hing and Mario Rocha now both BSc in Traditional Chinese Medicine and currently working as independent practitioners, and Ruth Kerr now BSc in Nursing who is employed within healthcare management in the private sector. We would also like to include the assistance given to us by Jessica Nelson, Omega Lasers UK, who taught us how to use the equipment provided and arranged for the laser to be made available and in a state of readiness. We extend our thanks to Jim Moore, our own University technician, who checked the equipment at regular intervals to make certain it was working satisfactorily and maintained the system that kept the researchers and participants blinded throughout the study. ■

Dr Catherine Kerr, PhD, MPhil. MEd, BSc. Cert Ed. RCNT. RGN, is programme leader for the Health Sciences at Middlesex University, Queensway, Enfield EN3 4SF. She studied science and worked extensively in acute clinical practice in many of the UK teaching hospitals. She has been in education for this last 15 years teaching and supervising nursing and Chinese medicine students. She has researched into the learning of science for application to clinical practice.

Dr Neil Spielholtz, PhD, PT, lectures in Fort Lauderdale University, Miami on the use of laser acupuncture for pain management. He travels extensively throughout the USA.

Paul Lowe, MSc. BSc. PGCE. RSCN. RGN MIBiol. CBiol., is the Programme leader for Complementary Medicine at Middlesex University, Queensway, Enfield EN3 4SF. He has studied science and has spent time in clinical practice. He teaches disordered physiology and clinical skills to Chinese medicine students and has been involved as clinical liaison with Beijing University Hospital over many years.

Address where study was undertaken: Middlesex University, Enfield Campus. UK

Address for correspondence:
Dr. Catherine M. Kerr, School of Health and Social Science, Middlesex University, Enfield Campus, Queensway, Middx. EN3 4SF UK
c.kerr@mdx.ac.uk

References

British Medical Association,. (2004). 'Acupuncture's place within mainstream medicine', Acupuncture in Medicine, 15, 104 -106.

Cheung, C. (1986). 'The treatment of cigarette smoking by electroacupuncture, intradermal needle and diet precautions'. British Journal of Acupuncture, 9, 27-28.

Choy D., Lutaker I., & Meltzer L., (1983). 'Effective treatment for smoking cessation', *American Journal of Medicine*, 75, 1033-6

Dept. of Health (2006). *The Health Act*. Publisher Dof H: London.UK

Han J., Terenius L. 1982 Neurochemical basis of acupuncture analgesia. *Annual Review of Pharmacology and Toxicology*. 22, p192-220 .

Karavis M. 1997 The Neurophysiology of acupunctre-a viewpoint. *Acupuncture in Medicine*. Vol 15, No 1 p 33-42.

Kerr C., Lowe P., Hing A. & Rocha M. (2000) 'Stop smoking using laser acupuncture', Issues in Health and Environment' 1, 16-22

Maravino T. (1984). 'Laser auriculotherapy as part of the nicotine detoxification process: evaluation of the 1280 subjects and theoretical considerations of a developing model', American Journal of Acupuncture, 16, 135-142

Martini F., Bartholomew E. (2003). *Essentials of Anatomy and Physiology*. 3rd ed. Pearson Educational International: Prentice Hall. New Jersey

Strauss S. (1987). 'The scientific basis of acupuncture', Australian Family Physician, 16, 166-169

Streiner D, Geddes J. (2001). 'Intention to treat analysis in clinical trials where there are missing data', Evidence Based Mental Health. 4, 70-71

Wen H. Cheung S. (1973). 'Treatment of addiction by acupuncture and electrical stimulation', Asian Medical Journal, 9, 138-41

White A., Filshie J. & Cummings T. (2001). 'Clinical trials of acupuncture: consensus recommendations for optimal treatment, sham controls and blinding', Complementary Therapies in Medicine, 9, 237-245