Effects of Laser Acupuncture Therapy in Pain Treatment

By

Wai Wong

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ABSTRACT

Abstract of thesis entitled "Effects of Laser Acupuncture Therapy in Pain Treatment"
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This thesis presents an investigation of the effectiveness of laser acupuncture. Laser acupuncture has been utilised as an approach for the treatment of pain that combines both traditional Chinese acupuncture and low-level laser therapy since its emergence in 1973. Its effects are not well understood and no standardised clinical protocol has been established. In this study, a diode laser (wavelength 680 nm, mean output power 30 mW) was used to irradiate four acupuncture points located on upper extremities over a 10-day period in order to investigate the effectiveness of laser acupuncture on treating pain. The laser acupuncture was applied daily and treatment lasted for three minutes on each acupuncture point. The median nerve conduction velocity was measured at 30-minute intervals on days one, five, and ten. Specifically, there were two independent experiments. The aim of the first was to study the effects of laser acupuncture on normal subjects. In this experiment, the effects of acupuncture were observed through an investigation of the changes of nerve conduction studies over time on eighteen normal volunteers. Results showed that motor nerve fibre was sensitive to laser acupuncture and there was a significant decrease in the motor conduction velocity after laser acupuncture ($p < 0.001$). It was also found that laser acupuncture resulted in a significant decrease in sensory nerve conduction velocity 30 minutes after application of laser acupuncture. The second experiment was conducted to investigate the efficacy of laser acupuncture on twelve patients with idiopathic bilateral carpal tunnel syndrome. Carpal tunnel syndrome is a common entrapment neuropathy with pain as the main symptom. Patients were given three sessions of laser acupuncture therapy with at least a week interval between successive sessions. Treatment outcome was quantified by patients' subjective feedback (McGill pain questionnaire, visual analogue scale) and objective measurements including physical examination, a grip-strength test, a pinch-

strength test, and nerve conduction studies. A randomised single-blind controlled trial was adopted for the first session. From the second session, both hands of patients received real laser acupuncture treatment. The results, except those of the pinch-strength test and the nerve conduction test, indicated that laser acupuncture could improve patient's condition ($p < 0.05$) after the first session. It was found that the patient's condition was improved more significantly ($p < 0.001$) after two or more sessions of laser acupuncture treatment. The results also showed that the amount of increase in motor nerve conduction velocity decreased with time and the sensory nerve conduction velocity increased with time. These results suggested that laser acupuncture could improve the condition of patients with idiopathic carpal tunnel syndrome. Further research is recommended to explore the clinically dominant position of laser acupuncture therapy on treating carpal tunnel syndrome or other diseases according to present therapeutic protocol. More research is also needed for the better understanding of the mechanism of laser acupuncture therapy.

Key words: low-level laser therapy, laser acupuncture, carpal tunnel syndrome, nerve conduction studies

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LIST OF ABBREVIATIONS

5-HIAA	5-hydroxyindoleaceticacid
Anti-SNCV	Antidromic sensory nerve conduction velocity
CTS	Carpal tunnel syndrome
CW	Continuous wave
GSS	Global symptom score
He-Ne	Helium-Neon
LA	Laser acupuncture
LLLT	Low-level laser therapy
MNCV	Motor nerve conduction velocity
NCSs	Nerve conduction studies
NCV	Nerve conduction velocity
Ortho-SNCV	Orthodromic sensory nerve conduction velocity
PW	Pulsed wave
SNCV	Sensory nerve conduction velocity
TCM	Traditional Chinese Medicine
TPs	Trigger points
VAS	Visual analogue scale

CHAPTER 1 INTRODUCTION

1.1 Background

The word LASER is an acronym for Light Amplification by the Stimulated Emission of Radiation. Laser was invented in 1960 by Dr. Theodore Maiman of Miami in the United States, though it was based upon principles originally outlined by Einstein in the early 1900s. Within a relatively short period of time, the applications of lasers were developed for many fields of medicine.

High intensity lasers, which have an output power range of 10 to over 100 watts, are used for surgical procedures. Low-level or low-intensity lasers, which have an output power range of 1 to over 100 milliwatts, have gone through the same exciting developments in many areas of medicine. They are used as a form of therapy for the treatment of open wounds, soft tissue injuries, and arthritic conditions, as well as for the management of pain. For example, low-level laser therapy (LLLT) is used in areas such as internal medicine, surgery, neurology, psychiatry, gynaecology, obstetrics, ophthalmology, dermatology, otorhinolaryngology, and acupuncture therapy (Kleinkort et al., 1984).

A great improvement in LLLT for clinical applications was largely based upon the early work of Dr. Endre Mester in Budapest, who demonstrated the potential of using relatively low output power density laser (< 5 W/cm^2) to stimulate certain biological processes and to aid wound healing. Laser photobiostimulation rapidly became a new treatment and form of rehabilitation. In 1973, Dr. Friedrich Plog recommended the use of low-level laser radiation as an alternative to metal needles in traditional acupuncture treatment. Based upon Plog's early work, a number of low-level laser systems were subsequently developed specifically for acupuncture treatment. Figure 1.1 depicts a diagram showing the development of laser acupuncture.

Acupuncture in its traditional form is based upon the stimulation of well-defined points on the body by the insertion of metal needles. Such needling is considered necessary to redress the balance of *yin* and *yang* and the flow of *chi*, or energy, which in classical acupuncture theory is considered to be disrupted when the body suffers from disease. This form of therapy predates modern medicine by several thousand years and has recently found

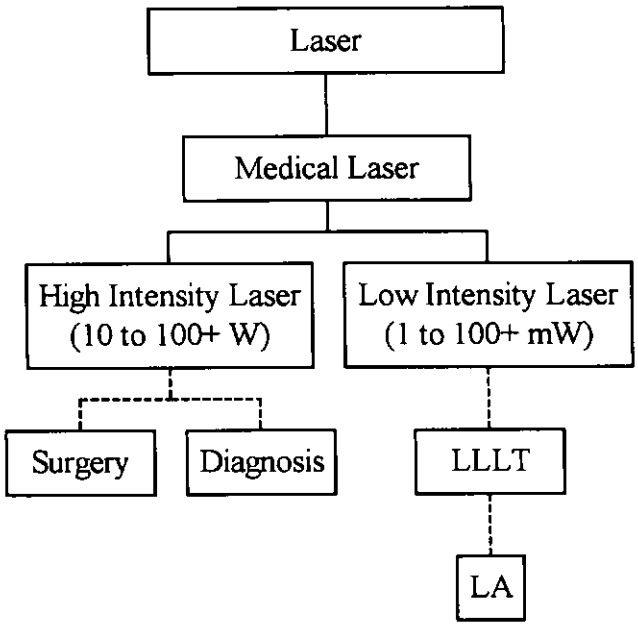

Figure 1.1. Diagram of the developmental history of laser acupuncture.

greatly increased acceptance in the West, at least as an effective analgesic therapy (Wong et al., 1992).

Laser acupuncture (LA) has some characteristic advantages over traditional acupuncture. These include the following:

a. It is aseptic and hygienic.

b. It is non-invasive and painless.

c. It has no reported side effects.

d. It is more acceptable to children or patients with a nervous or delicate constitution than traditional needle acupuncture.

e. It is easy to operate so there is a potential use for home treatments (Naeser, 1997).

Moreover, Brancok and Naeser (1999) stated that LA therapy might offer potential cost savings. They listed and compared the estimated cost of managing one case of carpal tunnel syndrome (CTS) using surgery and rehabilitation in the United States with the total cost of employing LA for the same case (estimated cost per case, $12,000 using surgery and

rehabilitation; using LA treatment, $1,000). They concluded that promoting LA therapy would result in government cost savings in the area of primary medical service.

LA has been used to treat a variety of pain disorders, including paralysis and spasticity in adult stroke patients (Naeser, 1997), postoperative vomiting in children undergoing strabismus surgery (Schlager et al., 1998), cystic hyperplrsia of the breast (Qiu et al., 1990), as well as other diseases. These include infantile diarrhoea, mumps, exophthalmic hyperthyroidism, hyperlipemia, and heart disease (Qin, 1987; Zhang, 1999). Among these applications of LA, the most obvious effect is its analgesic effect including relief of both acute and chronic pain.

Most researchers hold the positive view that LA is a new, safe, and painless method of treatment. However, there are some researchers who are sceptical and hold negative views concerning the reliability of LA treatment. They believe that there is a lack of specific effects produced by LA or that it merely acts as a placebo in their clinical practices (Devor, 1990; Gam et al., 1993; Lowe et al., 1997; Craig et al., 1999).

Although there are many physicians who apply LA in their clinical practice, the therapeutic protocols of LLLT are not standardised since the mechanism of LA therapy is not well understood. Thus, demonstrating the effectiveness of LA treatment with consistent treating parameters has become an important aspect of research.

1.2 Objectives

In this study, a diode laser was used to irradiate four acupuncture points located on upper extremities of the body in order to investigate the effectiveness of LA in pain treatment.

Specifically, there were two separate experiments in this study. One involved studying the effects of LA on normal subjects. In this experiment, the effects of LA were evaluated through an investigation of the neuroelectrophysiological changes.

The other experiment in this study involved studying the effects of LA on patients with carpal tunnel syndrome (CTS). CTS is a common entrapment neuropathy with pain as its main symptom. The objective of this part of the study was to assess whether LA therapy as a mono-therapy could improve the patient's condition.

1.3 Outline of the Thesis

A total of six chapters is presented in the thesis.

Chapter 1 is the introduction, which includes background information about LA therapy and its development, as well as the aims of the study.

Chapter 2 is a literature review covering four topics. Firstly, an introduction to LA therapy is provided, which involves reviewing previous LA therapy practices, known mechanisms of LA on analgesia, parameters used in LA applications, and the safety of LA. Secondly, the evaluation of pain management is described. This part introduces some of the evaluations for pain, which are used in our study. Thirdly, carpal tunnel syndrome is described in detail because the patients with this disease were recruited as subjects. Finally, nerve conduction studies are introduced because the measurement of nerve conduction velocity is used as the principal evaluation value in the study.

Chapter 3 presents the experiment conducted to assess the effects of LA on normal subjects. The experiment in this case is controlled. In both the controlled group and the treated group, the statistical procedure is applied to observe the effect of LA on normal volunteers.

Chapter 4 presents the experiment conducted to assess the effects of LA on patient subjects with chronic CTS. In this part, a randomised single-blind controlled experiment involving CTS patients is described, followed by the results and discussion.

Chapter 5 contains the conclusions of the whole study. Although Chapter 3 and Chapter 4 describe two different experiments, the aspects of both that relate to the effects of LA are discussed together.

A summary of the limitations of the study and recommendations for future work is outlined in Chapter 6.

CHAPTER 2 LITERATURE REVIEW

2.1 Laser Acupuncture Therapy

2.1.1 Introduction

Low-level lasers have frequently been used over the last 30 years in the treatment of various conditions including open wounds, arthritis, soft tissue injuries, and pain. Such a therapeutic modality is gaining widespread acceptance within the clinical profession (Baxter, 1994). Investigations have been conducted to study the feasibility of replacing traditional acupuncture therapy using needle by low-level laser therapy (LLLT).

Acupuncture is an important component of traditional Chinese medicine (TCM) and it has a long history. As early as the New Stone Age in China, primitive human beings used *bian* stone, which is considered to be the earliest acupuncture instrument, to treat diseases. Following the developments of productive forces, bone needle and bamboo needle appeared. Later, with the emergence of metal casting techniques, people began using metal medical needles, such as bronze, iron, gold, and silver. At present, stainless steel needles are most commonly used. However, following the development of modern scientific methods, some alternatives to metal needles have appeared, such as microwave, ultrasonic, and magnetic acupuncture (Wong et al., 1992).

The emergence of LLLT has facilitated the replacement of the classic acupuncture needle, thus providing a new type of treatment and adding the terminology "laser acupuncture" (LA) to the literature as early as 1973 with the work of Friedrich Plog in Canada (Navratil et al., 1997).

As a great discovery, one of effects of traditional Chinese acupuncture is attenuating pain. Thus, the topic of reducing pain by LA has begun to attract more interest. Indeed, at present, attenuating pain is the most important application of LA therapy.

.The mechanisms of both acupuncture and low-level laser therapy work are not well understood, although researchers have come up with many hypotheses. In actual practice,to relief pain in specific conditions, like carpal tunnel syndrome (CTS) has not been standardised. While there were many investigators who pointed out the positive effects of

LA therapy, there were those who had their doubts about the genuineness of the effects of LA therapy (Tuner and Hode, 1998).

This chapter will proceed with a brief look at the general development and application aspects of LLLT, followed by an overview of LA and its analgesic effects. Lastly, carpal tunnel syndrome (CTS) and nerve conduction studies (NCSs) will be discussed because patients with CTS are chosen as the subjects in this study and NCSs are the main evaluations to assess the analgesic effects of LA.

2.1.2 Previous Studies and Clinical Practices Concerning Laser Therapies

In most papers that discuss the reduction of pain by LLLT, the method described involves a laser beam irradiating the sore target points (Simunovic et al., 1998; Fukuuchi et al., 1998; Laakso et al., 1997; Simunovic et al., 1996). This is a therapy as same as acupuncture therapy, in which a needle inserts into the body at the point, called *Ashi* point, which is a distinct pain location but is not the conventional acupuncture point. Stimulating the *Ashi* point can result in a distinct analgesic effect. Consequently, using LLLT to reduce pain by irradiating target points should be considered as one type of LA application.

The effect of LLLT has been found to attenuate pain successfully and this has become the widest usage in the medical field. In the early days of this treatment, Walker (1983) used a Helium-Neon (He-Ne) laser (632nm, 1mW, 20Hz) on 36 patients with chronic pain (the pain had lasted for more than six months and most of the patients were neuralgia, some were osteoarthritis), conducting 30 trials of laser irradiation. He applied the irradiation on a 4mm^2 area of skin overlying peripheral nerves bilaterally for 20 seconds per site at a rate of three times per week during a 10-week period. Some patients were treated with accompanying 30 seconds irradiation on the painful nerve or joint to produce an analgesic effect. He observed that laser irradiation could cause a large concentration increase in the urinary excretion of 5-hydroxyindoleacetic acid (5-HIAA), which was a degradation production of serotonin. Such a high level of 5-HIAA might be a harbinger of analgesia, while such an alteration in serotonin metabolism might be a prerequisite for long lasting pain relief. Walker's finding represented a milestone in LLLT research into relief pain and his study encouraged more researchers to focus on this field. Goldman et al. (1980)

demonstrated that patients with rheumatoid arthritis who received LLLT showed marked improvement in their arthritis in terms of both activity and relief of pain. Using the same laser source and a similar treatment protocol, Walker's group (1988) found that LLLT might provide relief from pain associated with trigeminal neuralgia. With the purpose of attenuating pain, Costantini et al. (1997) performed treatment on 714 patients with crania-facial pain. They applied steel inox needles, variable in diameter and length, for about 20 minutes with the number of applications ranging from 10 to 20. Except needle acupuncture, they combined an electro-stimulation therapy or laser therapy. The authors emphasised that the best results were achieved with patients who chose acupuncture as the first therapeutic approach, and asserted that laser irradiation represented a harmless and effective treatment of such a diffuse and invalidating disease. Irradiating on trigger points (TPs) and combining scanning using laser, Simunovic et al. (1998) treated 324 patients with medial and lateral epicondylitis. They demonstrated that the best analgesic effect and improved functional ability were obtained using a combination of treatments. Moreover, a GaAlAs diode laser (output power 60mW, spot size 2 mm) was used on target points to treat 3,635 patients with various kinds of pain in a non-controlled study. The researchers found that the data were meaningful and confirmed an overall LLLT effectiveness rate of 76% for those patients suffering from chronic pain (Shiroto et al., 1989). Weng (1986) maintained that the analgesic effects induced by a therapeutic laser applied to specific acupuncture points were sufficient for performing minor surgical operations and that such laser treatment provided better muscle relaxation than classic needle acupuncture. Even more impressive successes have been achieved in oral surgery.

Conversely, however, some researchers received consistent results that no significant differences were observed between the laser and the placebo group in the treatment of lateral epicondylitis (Craig et al., 1999; Devor, 1990; Lowe et al., 1997; Lundeberg et al., 1987; Haker et al., 1990; Krasheninnikoff et al., 1994).

In 1986, Basford (1986) stated that research studies on the effects of LLLT on the biologic function were growing through laboratory and clinical studies. He pointed out that no universally accepted theory had been proposed to explain the mechanism of either "laser analgesia" or "laser bio-stimulation." Thus, from a critical angle, Basford posed the

unanswered question of whether LLLT offered hope, or merely "hype and hokum." In 1989, Basford summarised the results of a study on the effect of low-level laser irradiation on cell function. He maintained that any effects produced by low-level lasers might be due to the effects of light in general and not to the unique qualities of lasers. The view's foundation depended on the polarisation and coherency character of laser irradiation, which was attractive as sources of biological effects, since resonant effects might be hypothesised to occur in the interaction of laser radiation and cellular components. However, non-laser light sources could cause stimulative effects (Karu, 1987; Kana et al., 1981) and tissue scattering, whilst fibre optic delivery systems used in many experiments rapidly degrade coherency (Basford, 1989). In 1993, Basford and his colleagues used an IR diode laser (830nm wavelength, 40mW output power, continuous wave) to irradiate for a period of 30 seconds at 10 points located along the course of the median nerve on 33 normal subjects. The test was controlled, using an active (1.2J/point) irradiation for the treated group and an inactive (0J/point) irradiation for the controlled group. They found that the diode laser irradiation could affect median nerve function but that the effects appeared to be limited to the distal portion of the nerve (Basford et al., 1993). In 1995, in a review article, Basford confirmed that besides laser irradiation's being able to modify cellular processes in a wavelength-dependent non-thermal manner, intensities sufficient to produce these effects on cells can be delivered to the superficial joints and tissues typically treated by LLLT. But concerning the view that LLLT had become a clinical tool, Basford maintained a negative position (Basford, 1995). In 1999, Basford and his group assessed the effectiveness of LLLT on musculoskeletal low back pain. In this double-masked, placebo-controlled, and randomised clinical trial, they used a 1,060nm Nd:YAG continuous wave laser with a 2.5cm diameter with an average intensity of 542mW/cm^2 to irradiate for 90 seconds at eight symmetric points along the lumbosacral spine three times per week for four weeks on 63 patients. They found that this treatment could produce a moderate reduction in pain and an improvement in the function of the limb concerned, but the effectiveness was limited and decreased with time. Basford concluded that LLLT was used in as many as 30-40% of physical therapy, dental, and sports clinics to treat soft tissue injuries, healing wounds, pain, and inflammation. He also stated that the laser in common use had increased in power from 30 to 100mW

(Basford et al., 1999). Reviewing the researching course of Basford and his colleagues, it is obvious that Basford has a progressive procedure to accept LLLT. If he could change his treatment parameters in 1993 and 1999, including increasing treatment dosage and treatment sessions, maybe the results would be more satisfactory.

Tuner and Hode (1998) reviewed 1,400 articles on LLLT, which in general emphasised double-blind studies. In their conclusion, they listed a number of reasons what could cause the negative findings, including extremely low doses, faulty inclusion criteria, inaccurate control group definition, ineffective methods of therapy, inadequate attention to systemic effects, tissue condition, and improper power density. Tuner and Hode pointed that it was necessary to unify treatment protocols. Additionally, they mentioned that a non-contact laser technique was applied in some of the research studies. If this was the case, the real therapeutically power applied to the patient was different to be calculated and recorded.

Consequently, LA therapy has been accepted gradually but further research is necessary for it to be developed and improved.

2.1.3 Possible Mechanisms of Laser Acupuncture Treatment on Analgesia

The mechanisms for both LLLT and LA are not completely understood. However, many studies have demonstrated some evidence on this aspect, which are presented below.

Mester and his colleagues have carried out many studies in this field over a 20-year period. They found that low-level lasers were effective in the treatment of various types of wounds and this effect depended on collagen production, succinic acid dehydrogenase, lactic acid dehydrogenase, and non-specific esterase activities of the fibroblast cultures (Wester et al., 1971, 1982, 1985).

In 1980, Goldman et al. suggested that cells or sub-cellular components of cells, selectively absorbed laser light based on pigmentary differences. They indicated that this absorption was dependent on the wavelength used with different effects seen in various levels of tissues. There was also a possibility that laser radiation could be immunosuppressive, and therefore decreased some of this over-activity, especially that of the B lymphocyte line. The laser light might also affect the rheumatic pathological process (Goldman et al., 1980).

In 1983, Walker found that irradiation caused an increase in the urinary excretion of 5-hydroxyindoleacetic acid (5-HIAA), a by-product of serotonin metabolism that is consistent with patients' pain relief (Walker, 1983). Choi et al. (1986) similarly found that laser bio-stimulation increased the level of urinary 17-hydrocy-corticosteroids.

In 1984, Kleinkort et al. proposed one mechanism of the action of laser bio-stimulation that was based on the Arndt-Schultz law: "Weak stimuli excite physiologic activity, moderately strong ones favor it, strong ones retard it, and very strong ones arrest it" (Stedman's Medical Dictionary, 1982). Low-level laser stimulation, being a weak stimulus, may excite physiologic activity to produce stimulative effects in the form of pain relief and tissue healing. Moreover, low-level laser therapy has been described as having a stimulative effect on human tissue at a local cellular level and/or a general systemic level by accelerating the photo-biological or photochemical process (Kleinkor et al., 1984).

In 1988, Snyder-Mackler et al. reported a statistically significant increase in the latency of the superficial radial nerve corresponding to a decrease in sensory nerve conduction velocity after laser therapy. This suggested interference in sensory nerve transmission as a possible mechanism of action for laser analgesia (Snyder-Mackler et al., 1988).

In 1994, Baxter reviewed the analgesic effects of LLLT. The relative mechanisms of these effects included:

a. an increase in the levels of β-endorphin in the spinal liquor;
b. an increase in the urinary excretion of the glucocorticoid-inhibitor of β-endorphin synthesis;
c. an increase in the pain threshold through a complex electrolytic block mechanism of nerve fibres — the permeability of the membrane of the nerve cells for Na/K is decreased causing hyper-polarisation;
d. an increase in lymphatic flow and a reduction in edema;
e. an improvement in the local micro-circulation and an increase in the oxygen supply to the hypoxic cells and in the target point areas — the asphyxia of the tissue is reduced to a minimum and the removal of collected waste products takes place at the same time;

f. an alteration in the noradrenalin-adrenalin balance; and

g. a reduction in the release of chemical substances like bradykinin, a potent analgesic agent that normally irritates the receptors of the nerve and causes pain; histamine, a powerful inflammatory and analgesic agent; and acetylcholine, another analgesic agent that is blocked through an increase in acetylcholinesterase activity. (Baxter, 1994)

In 1999, Branco et al. pointed out that a possible mechanism for the effectiveness of LA could be an increase in adenosine triphosphate (ATP) on a cellular level, a decrease in inflammation, and a temporary increase in serotonin (Branco et al., 1999).

In addition to the above experimental results, some modelling deductions have been made. For example, in 1996, Li and his colleagues described the pressure effects of LA based on the theory that light waves have a dynamic effect. They demonstrated that it was the mechanical force of LA derived from the light pressure that caused reaction with tissue. This was a new idea regarding the mechanism of LA. Light pressure is determined by the magnitude of laser output power, the irradiation time, the light beam spot size, and the direction of reaction. In other words, changing the above parameters can change the light pressure used on the point, which mimics an assortment of manipulations, namely, lifting, thrusting, twirling, rotating, plucking, flying, and retaining (Li et al., 1996).

2.1.4 Parameters of Physical Aspects of Laser Acupuncture Treatment

Laser light possesses monochromatic, highly directional, and coherent characteristics that are very different from those of ordinary light. These characteristics make a laser light beam a controllable and effective method of treatment. The basic characteristics of laser light that are used in LA are described below.

Wavelength

The biological effect of LA is significantly related to the wavelength of the laser. This idea has been demonstrated by a number of researchers.

In the beginning of LLLT application, He-Ne laser was most commonly used. This form of laser has a wavelength of 632.8 nm (Walker, 1983; Brockhaus, 1990). At present,

other wavelengths commonly used for LLLT or LA include, 635 nm, 650 nm, 660 nm, 670 nm (InGaIP lasers) (Laakso et al., 1997; Branco et al., 1999), 780 nm, 810 nm (Fukuuchi et al., 1998), 820 nm, 830 nm (GaAlAs lasers) (Krasheninnikoff et al., 1994; Wong et al., 1995; Simunovic, 1996; Lundeberg et al., 1997; Simunovic et al., 1998), 904 nm (GaAs lasers) (Hansen et al., 1990; Klein et al., 1990; Haker et al., 1990; Ottar et al., 1992; Soriano et al., 1998; Branco et al., 1999), and 1,060 nm (CO_2 lasers) (Tuner et al., 1998). Of course, every laser wavelength produces both positive and negative treatment results.

Frequency

The various treatment methods all use one of two types of laser: continuous wave (CW) and pulsed wave (PW).

A CW source is one that emits a constant (or slowly changing) power for a period longer than about 0.5 seconds. In contrast, a pulsed source emits a series of pulses, which in general have a power varying greatly over the length of the pulse. The pulses are very short with intervals that are usually much longer than the length of the pulses (King, 1990).

In previous studies, CW or PW lasers were used without special reason. The range of applied frequencies included 20 Hz, 70 Hz, 1,000 Hz, 5,000 Hz, and 10,000 Hz. There is no particular reason for choosing any one frequency over another. It may ultimately depend upon who manufactured the unit's control systems.

Output Power

Output power is a physical parameter of the equipment's accuracy. From a review of previous recordings of the output power of LLLT, it is clear that there is an increasing tendency for researchers to use an output power of more than 1mW. In Walker's pioneering study, a 1mW He-Ne laser was able to produce the effect of pain relief (Walker, 1983; Walker et al., 1988). However, other researchers have applied a higher output power in excess of 10 mW. Wong et al. (1995) used a 100 mW GaAlAr laser (wavelength 830 nm) to irradiate the tips of the spinous process between C5 and T1 for two to five minutes over 10 treatment sessions in order to treat CTS. Kemmotsu (1998) used first a 150 mW laser and then a 60 mW laser for three minutes to treat postherpetic neuralgia (PHN). In fact, some

researchers are sceptical about the therapeutic effect of a laser with as low an output as 1 mW.

Output power is relative with an important element of treatment, dose. Output power will be mentioned again in the section of discussion on laser therapy dose.

2.1.5 Clinical Factors of LA Treatment

Penetration

The problem of laser light penetration is the most important of these factors. In order to examine the opinion that LA is useful in the relief of deep-seated pain or that it can reach deep acupuncture points, it is necessary to know how far laser light will penetrate into tissue.

For the acupuncture operations of TCM, it is very important to insert the needle into the body to a specific depth. This is so essential because the needle must stimulate the point in order to have a therapeutic effect. According to the principles of TCM, the depth of the needle insertion depends on the pathological conditions, the location of points, and the different constitutions and body types of patients. In the practice of LA, the depth of penetration is also an important factor in deciding whether it can stimulate the acupuncture point in order to cause the expected therapeutic effect.

In some of the literature supplied by manufacturers of commercial systems, it is claimed that visible red laser light of around 630 nm will penetrate 5-10 mm of tissue, while near-infrared wavelengths in the 850-1,000 nm range will penetrate as far as 30-40 mm. According to other published data concerning measurements of postmortem human tissue or in vivo animal tissue, however, the depth of penetration of a laser light with a wavelength of 630 nm is in the range of 1-2 mm. At 800-900 nm the penetration is approximately twice as large. Besides, it is indicated that 5-10 mm represents the range of depth to which at least 1% of the incident energy of red light may penetrate, while a negligible fraction of near-infrared light can penetrate as far as 30-40 mm into tissue (King, 1990).

Following laser radiation contact with the surface of human skin, common physical reactions including reflection, absorption, and dispersion occur. Goldman et al. have found that 99% of laser radiation will be absorbed into the skin. This absorption will occur in at least the first 3.6 mm of tissue (Goldman et al., 1971). If tissue is irradiated at levels below

that where tissue evaporation begins, 100% of the impulse will be absorbed. This is a percentage minus the reflected value. The He-Ne laser directly penetrates 0.8 mm and indirectly penetrates 8-10 mm of tissue (Kleinkort et al., 1984).

Kolari studied skin transmissions for low-level laser light. The skin samples used were breast surgical skin specimens (the sample was cut to a thickness of 0.5-1.8 mm using a microtone) or dermatomic slices (with a sample thickness of less than 0.4 mm) cut and prepared for immediate study. Samples were irradiated by He-Ne laser light (632.8 nm) and by a GaAlAs (820 nm) diode infrared laser light. Light transmitted through the samples and incident light were measured using a silicon PIN photodiode. The following equation was used to calculate transmission:

$$T=I_z/I_o*100\%,$$

where T is the percentage transmission, I_z is the total energy transmitted through a skin sample of thickness z, and I_o is the incident energy. Transmissions were analysed using a cutaneous model with a superficial capillary plexus of 0.1 mm at a depth of 0.4 mm. The result was that transmissions were highly exponential as the function of depth for both the He-Ne and GaAlAs lights at both the superficial and deep dermal layers (Figure 2.1). The correlation coefficients were 0.97 for both the He-Ne laser and the GaAlAs laser diode. Table 2.1 shows the depth of penetration into human skin of the He-Ne and GaAlAs lights. The transmission of light from the GaAlAs laser diode was approximately 1.6 times that of the light from the He-Ne laser. The magnitude of penetration was compared with data from earlier studies (Anderson et al., 1981; Hardy et al., 1956). The conclusion reached was that the depth of penetration might increase with an increase of the laser light wavelength (Kolari, 1985). In 1993, Kolari et al. (1993) carried out similar studies and got the same result. They announced that the penetration of the laser beam was only a few millimetres in deep tissue layers, and could be attained for only a very small part of the whole dose of laser irradiation. Because blood is highly absorbent of light with a wavelength over 630 nm (Grush et al., 1984; Mckenzie et al., 1984), the dermal vascular plexus should absorb the laser light. Thus, it was possible that the laser effects would be mediated by electromagnetic receptors. Kolarova et al. (1990) verified that as the wavelength increases into the visible and near-infrared optical region of the spectrum, radiation penetrates more deeply into the skin.

Moreover, they used a He-Ne laser (wavelength 632.8 nm, output power 50 mW) and a semiconductor laser (wavelength 675 nm, output power 21 mW) in their experiment. They found the transmission in granular tissue was about 2.5 times higher than that in normal skin. In the thickest skin sample (2 cm), approximately 0.3% of He-Ne laser and 2.1% of semiconductor laser light penetrated. This indicated that the transmission of optical radiation in human skin depends on many individual factors, including different skin layer for each skin and different localisation on the skin surface. This is a decisive factor in the selection of the radiation dose (Kolarova et al., 1999). The samples in this study were obtained from different individuals who were undergoing plastic surgery on different body areas, and the specimens were treated immediately after removal and kept in a moist chamber at all times.

It is currently an accepted theory of laser light penetration that the depth of penetration varies with tissue type and wavelength. It is also believed that in clinical practice, the higher the power density, the deeper the penetration will be even if the wavelength is the same (Baxter, 1994).

Based on the above theory, it is obvious that the penetration of LA will not be sufficient for treating pain if the depth of penetration depends only on the wavelength of the laser light. Using a correct power density is helpful to cause the effect for LA therapy. Besides, it is another important factor to choose the acupuncture point (situated along meridians in the body).

It is not well known that systemic theory concerning the mechanisms of Traditional Chinese Medicine. One of the established theories in relation to acupuncture is that the skin overlying the acupuncture point possesses a character of low resistance. Therefore, it is possible that the same LA will irradiate the special point to penetrate deeper than the surrounding tissue.

Dose

As well as the penetration of LA, the magnitude of the dose must also be taken into consideration.

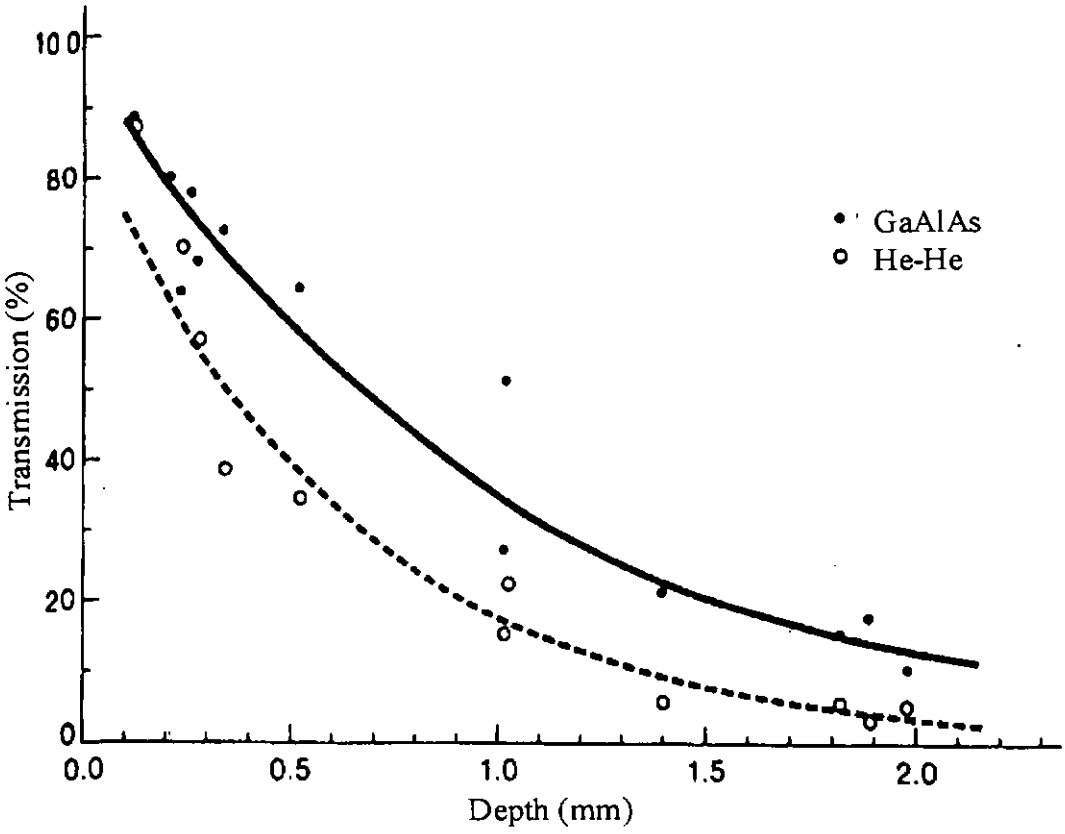

Figure 2.1. Total transmission of the skin for unfocused helium-neon laser light (633 nm) and infrared laser-diode light (820 nm). (From Kolari, 1985)

Table 2.1. Penetration depth (μm) of light from the different wavelengths (nm) laser diode compared with the previous findings (Reproduced from Kolari 1985)

Transmittance (%)	Kolari's findings (1985)		Anderson's findings (1981)			Hardy's findings (1956)	
	632.8 nm (He-Ne)	820 nm (GaAlAs)	600 nm	700 nm	800 nm	700 nm	1,230 nm
63	210	370	270	330	560	240	540
37	540	890	560	730	1,190	680	1,140
13.5	1,160	1,910	1,110	1,480	2,360	1,510	2,280
5	1,770	2,910	1,650	2,230	3,520	2,340	3,400
1	2,760	4,520	2,530	3,670	5,400	3,670	5,230

A. Calculation of the Dose

In clinical treatment, the dose can be described as the energy or the energy density.

LLLT devices are generally specified in terms of the average output power (milliwatts), wavelength (nanometres), and the radius (centimetres) or beam area (cm^2) of laser light.

The output power of a laser, measured in milliwatts (mW), refers to the number of photons emitted at the particular wavelength of the laser diode. The power density measures the potential thermal effect of those photons on the treatment area. It is a function of laser output power and beam area, and is calculated as:

$$Power\ density\ (W/cm^2) = \frac{Laser\ output\ power\ (W)}{Beam\ area\ (cm^2)}.$$

Beam area can be calculated as:

$$Beam\ Area\ (cm^2) = \pi \times Radius\ (cm)^2.$$

The total photonic energy delivered into the tissue at a particular output power over a certain period is measured in the unit of Joules, and is calculated as follows:

$$Energy\ (J) = Laser\ output\ power\ (W) \times Time\ (Sec).$$

For a given wavelength of light, energy density is the most important factor in determining the tissue reaction (Baxter, 1994). Energy density is a function of power density and time in seconds, and is calculated as:

$$Energy\ density\ (J/cm^2) = \frac{Laser\ output\ power\ (W) \times Time\ (Sec)}{Beam\ area\ (cm^2)}$$

$$Energy\ density\ (J/cm^2) = Power\ density\ (W/cm^2) \times Time\ (Sec).$$

B. Therapeutic Dosage in Previous Studies

When reviewing previous therapeutic dosages, it was very difficult to compare the dosages used because most of the papers did not indicate relative parameters (i.e. spot size) for calculating accurate energy density or energy given to the subjects. Besides, it was difficult to calculate the dosages used for the research applied non-contact techniques. For example, Lundeberg et al. in 1987 used a laser probe held 1mm away from the patient's skin and applied a laser therapy dosage of 0.0042J/point—though the real dosage was distinctly smaller (Lundeberg et al., 1987).

In a number of papers demonstrating positive analgesic effects in clinical application, used energy density is very small. Walker (1983), for example, used 0.005 J/point and Snyder-Mackler et al. (1986) used 0.01 J/point. However, their results attracted both optimism and scepticism.

In general, many poor results found in routine clinical practice or in research trials are typically associated with the use of inappropriately low dosages. Does this mean that a higher dosage is better? Not necessarily. The relationship between the therapeutic laser dosage and the therapeutic result is not so simple. One explanation for this relationship is based on the Arndt-Schultz law of photo-biological activation (Figure 2.2) (Baxter, 1994). This points out that too low stimulation will give poor results and too high stimulation will cause an inhibitory effect. Thus, choosing an appropriate dosage is very important.

In summary, there is not currently a distinct standard threshold of therapeutic dosage in LA therapy. However, it is necessary to establish one or a standard system to facilitate clinical protocol. Such a standard can only be determined by further research.

Skin Temperature

Low-level lasers are not able to raise the temperature in the irradiated tissues by more than 1°C (Jarvis et al., 1990).

Basford (1989) maintained that LLLT took place at irradiation intensities so low that any occurring biological effects were due to the direct effects of radiation rather than heating. He also pointed that irradiation induced temperature elevations should be minimal, perhaps not more than 0.1-0.5°C. In a later paper (1993), he reported there were no significant differences in temperature between those subjects treated by the laser and control groups following irradiation.

In conclusion, during the treatment of LA to relieve pain, the change of skin temperature caused by LA can be ignored.

De Qi

Why must the issue of *De Qi* be discussed in this section? In the application of needle acupuncture, the phenomenon known as *De Qi* is the main evidence for the doctor

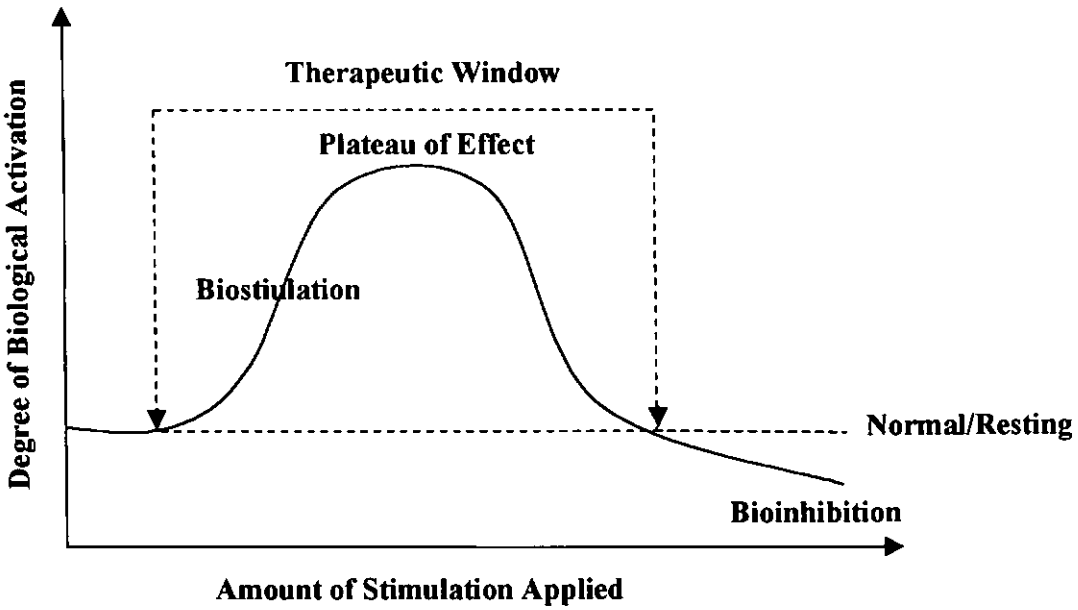

Figure 2.2. Schematic representation of the Arndt-Schultz law. (From Baxter, 1994)

and patient that the needle has reached the proper location. Specifically, the doctor may feel tenseness and a dragging sensation around the needle while the patient may have soreness, numbness, a sensation of distension or heaviness around the point, even feelings of cold, warmth, itching, or pain, or the sensation of having an electric-shock or an ant crawling over one's skin. According to the theory of TCM, *De Qi* is necessary for the efficacy of acupuncture (Chang, 1979; Essentials of Chinese Acupuncture, 1980).

Most writers researching LA have found that the irradiation receiver had no feeling during the therapeutic period, even demonstrating that LA had effective therapeutic qualities (Qin, 1987). In most of the literature expounding LA as a significant analgesia, the issue of *De Qi* is not raised (Wei, 1980; Kroetlinger, 1980; Bischko, 1980; Kreczi et al., 1986; Branco et al., 1999). For sceptics, the fact that LA can not evoke the characteristic needling sensation of *De Qi* explains why LA is ineffective (Brockhaus et al., 1990).

However, some research has indicated that the *De Qi* phenomenon does exist during LA, but that it depends on the LA irradiation is applied on accurate locations where are chosen based on the theories of meridian and acupuncture (Xue et al., 1989).

When applying needle acupuncture, *De Qi* is an important source of information with which to evaluate its effect. When a laser light replaces the needle and seeks to produce similar effects, according to the theory of TCM, the patient feels the special sensation through his or her meridians because some acupuncture points have received laser light stimulation. However, the problem needs to be researched further.

The Safety of LA Treatment

Since its emergence, LA therapy has been considered a relatively safe technique. This section will present the topic of LA as a safe therapeutic method from two angles. First, the fact that the laser employed in LA therapy is safe enough for the human body will be discussed. Compared with needle acupuncture treatment, the accidents that can be caused by LA therapy are easily avoided and controlled. The second issue to be addressed relates to the fact that none of the relative research studies that have been reviewed have reported any side effects at all as a result of LA therapy.

A. Possible Accidents

Lasers are classified into four groups according to an internationally agreed system. Low-level lasers in the output power range of 5-500 mW are classified by the Food and Drug Administration (FDA) as class III B lasers (U.S. Department HHS, 1985). A laser of class III B is capable of injuring the eye upon contact with the laser beam or specular reflection exposure, but poses relatively little potential danger to exposed skin. In current clinical practice, any physician or operator must be familiar with the laser safety regulations to avoid the laser beam or laser specular reflection irradiation landing directly on the eye. Goggles are the most common laser protective measure.

Traditional acupuncture treatment, on the other hand, frequently causes some accidents, sometimes having serious results.

Traditional acupuncture therapy has been accepted by the general public because of its good curative effect. But possible accidents may occur as the result of unskilful manipulation by the operator or a special condition of the patient. The possible accidents include:

a. Fainting

This may be caused by improper posture, nervous tension, a patient's delicate constitution, or an operator's overly forceful manipulations. The manifestations in the patient are sudden dizziness, nausea and vomiting, pallor, palpitations, shortness of breath, a drop in blood pressure, cold extremities, and a thin, rapid, or deep-sited pulse. In severe cases, there may be loss of consciousness, sudden fall cyanosis of lips and fingernails, or faecal and urinary incontinence.

b. Stuck Needle

This condition is an abnormal situation in which after the needle has been inserted and retained it becomes difficult or impossible to manipulate, for example, by twirling, lifting, or thrusting.

c. Bent Needle

This is due to unskilful or too forceful manipulation, or to the needle's striking some hard tissue, or to an inappropriate change in the patient's posture after the insertion of the needle. It can also be caused by a collision of the handle of the needle with some external force, or by any improper management of a needle that is already stuck.

d. Broken Needle

This may arise from an overly strong manipulation of the needle after insertion, from strong muscle spasm, or from a sudden movement of the patient when the needle is in place. It is basically due to the poor quality of the needle or erosion of the needle root.

e. Hematoma

This is due to the needle's impaling the blood vessel during insertion.

f. Pneumothorax

When the needle is applied to the points overlying the area of the lungs, an improper direction, angle, or depth of the needle may injure the pleura and lung causing air to enter the thoracic cavity and leading to pneumothorax.

B. Side Effects

Researchers of LLLT and LA mostly agree that, except for the possible damage to the retina as a result of improper laser operation, LA therapy is safe and does not cause any side effects.

There are a few articles, however, that mention some possible side effects of LA. Chan et al. (1999) found that three patients out of 149 in their clinical research expressed discomfort during and after laser irradiation therapy. The first two patients recovered after a short rest, so their reaction might be due to nervous tension. The third patient, who was 74 years old, was in the rehabilitative duration after a craniocerebral operation and was also suffering from other serious diseases. The patient's irradiation therapy was suspended due to serious original diseases.

Although there are no distinct proven side effects, as a general precaution many investigators avoid giving LA to pregnant women, cancer patients, sufferers of acute haemorrhages, those with growth plates, or those who have photosensitive skin (Basfor, 1995). Perhaps it is considered that these people have special conditions that can affect or delay normal treatment or research, but there is no evidence to indicate that LA would be dangerous for them.

In summary, as any therapeutic method, the basic principle is not to hurt the patient. This decides that the safety of LA is the most important aspect during its application. Although the operation of LA is safer and easier than needle acupuncture, prevention of ocular damage must be ensured.

2.2 Evaluation of Pain

Another important concept of this study will be addressed in this section, namely pain, as well as its general measurements.

2.2.1 A General Introduction to the Subject of Pain

The concept of pain is broad. Pain is induced not only by exogenous stimuli and endogenous pathophysiological processes, but also by subjective perception, which varies considerably from individual to individual. Generally speaking, pain is an unpleasant sensory-based perception that is normally connected with actual or potential damage to the tissue, although this is not so in certain special instances.

The Western Medical Theory of Pain

In Western medical theory, the extremely common but elusive phenomenon of pain is regarded as a sensation that depends on its own specific sensory apparatus. The receptors in the skin and seep structures are fine, freely branching nerve endings that form an intricate network. A single primary pain neuron with its cell body in the posterior root ganglion subdivides into many small peripheral branches to supply an area of skin of at least several square millimetres. The cutaneous area of each neuron overlaps with those of other neurons so that each area of skin is within the domain of two to four sensory neurons.

The sensory nerve fibres for pain course through the entire body and are accompanied by motor fibres. They enter the spinal cord and brain stem through the posterior roots and the cranial nerves respectively. As the posterior root fibres enter the spinal cord, they terminate in the posterior horn of grey matter. There they synapse with the secondary sensory neuron, the axone of which ascends and crosses the anterior commissure of the spinal cord within three to four segments to find its place in the anterolateral spinothalamic tract. The anterolateral spinothalamic tract continues upward to the posterolateral nucleus of the thalamus in the brain. This tract lies in the anterior part of the spinal cord and passes through the retro-olivary part of the medulla and the dorsolateral parts of the pons and the midbrain. There appears to be a great diminution in the number of fibres as the tract ascends, which means that many of the ascending fibres terminate in structures located in the brain stem. The thalamic termination of the spinothalamic tracts and the secondary trigeminothalamic tracts synapse with the third sensory neurons that project to the cortex in the parietal lobes of the brain.

The pain-sensitive structures in the viscera and skin of the body, the mechanisms of their stimulation, and the transportation are believed to depend on neural transmission.

The Traditional Chinese Medical Theory of Pain

In Traditional Chinese Medical theory, a different terminology from that of the Western is used to describe the concept of pain.

The mechanism of pain is seen as a blockage of *chi* in a particular meridian that results in disharmony in the related organ. Similarly, dysfunction in the organ disrupts the

flow of *chi* in the related meridian. Each organ is associated with one of the two natural elements of *yin* and *yang* and *five elements* theory. If any one factor disrupts the normal balance, pain will result.

2.2.2 Pain Measurements

The feeling of pain is an unpleasant and complex perception, and it is difficult to make an objective standardisation to measure it. But what is more important is the patient's subjective expression for evaluating his or her feeling of pain. There are a wide variety of approaches to record the subjective description of the patient. They include the McGill pain questionnaire (MPQ) and the visual analogue scale (VAS), both of which are used in this study.

The McGill pain questionnaire was designed by Melzack in 1971. The questionnaire includes a list of words arranged in 20 groups that is offered to the patient to describe his or her pain. Since its emergence, the questionnaire has become a common measurement employed in both clinical evaluations and in laboratory studies. Thus, it has been translated into many languages, for example, German (Stein et al., 1988), Italian (De Beneditlis et al., 1988), Norwegian (Strand et al., 1997), Swedish (Burckhardt, 1994), and Chinese (Nan, 1994). In this study, the Chinese version of the questionnaire was employed.

The VAS is another widely used method of assessing pain in both clinical applications and experimental practice. It was first used in 1966 by Bond and Pilowsky. Basically it consists of a strip of paper on which there is a line 10cm long. One end is marked "no pain" and the other end is marked "the worst pain." Between these two points, the three words "mild," "moderate," and "severe" are marked on the line at equal intervals. At any time, the patient can point to the mark that best describes the degree of pain he or she is experiencing. The VAS is regarded as an extremely useful and quick method for evaluating the effects of any analgesic treatment, and is also considered to be one of the best methods available for measuring the intensity of pain (Scott et al., 1976). Aun et al. (1985) have observed that the VAS could be used with Chinese patients and yield a relatively high degree of accuracy.

2.3 Carpal Tunnel Syndrome

2.3.1 General Introduction

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy in the upper extremities due to compression of the median nerve. It was originally identified by Paget in 1854 and was later defined as a specific syndrome by Phalen in 1966.

2.3.2 Pathology

The carpal tunnel is bounded by the carpal bones and the transverse carpal ligament. A lot of conditions can cause an increase in carpal tunnel content resulting in nerve compression. The most common of these are chronic fibrosis and tenosynovial thickening.

2.3.3 Etiology

The etiology of CTS is completely unknown but some diseases and occupational factors can cause it. The diseases include rheumatoid arthritis, inflammatory synovitis at the wrist, diabetes, and hypothyroidism. The occupational activities include repetitive finger and wrist flexion that may precipitate or aggravate CTS. CTS occurs more commonly in workers whose work involves repetitive hand movements, such as typing on a computer keyboard, operating machinery, and assembly line work. Pregnancy can also cause CTS due to neural oedema (Wand, 1990).

2.3.4 Symptoms

Symptoms begin with intermittent paresthesias of the hand involving the thumb, the index and long fingers, and the radial aspect of the ring finger. The patient will complain of symptoms throughout the hand, although most can distinguish a more accurate distribution with careful observation. Pain often wakes the patient up at night from deep sleep and causes the patient to shake his or her hand to reduce the pain. This nocturnal exacerbation becomes a typical symptom for CTS. The pain can sometimes extend to the elbow.

2.3.5 Diagnosis

A consensus on diagnostic criteria for CTS is currently lacking. Physical findings are minimal, except in the later stages when atrophy of the thenar muscle may be present or sensory changes may occur. Tinel's sign or Phalen's sign may also be present. Tinel's sign refers to the reproduction of pain and paresthesias by tapping on the median nerve at the carpal tunnel. The Phalen test is performed with 60 seconds of complete wrist flexion, which produces pain and paresthesias if the syndrome is present. Besides, nerve conduction studies are the primary definitive test because CTS caused the progressive slowing in median nerve conduction velocity (Fullerton, 1963).

2.3.6 Treatment

The therapeutic management of patients with CTS varies according to the type of treatment. This section gives details of the different treatments available.

Conventional Therapies

According to the principles of Western medicine, treatment of CTS begins with conservative therapy followed, if necessary, by surgical procedure.

Conservative therapies include the use of a night splint that positions the wrist in a neutral position, nonsteroidal anti-inflammatory drugs, hypothyroidism, corticosteroid injections into the carpal tunnel, and occupational therapy for work-related cases.

For patients with thenar muscle weakness and atrophy, prolonged symptoms, or a lack of response to conservative therapy, surgical decompression either by open carpal tunnel release or endoscopic procedure is necessary.

Laser Acupuncture Therapy

Although CTS is considered the most common entrapment neuropathy, a few researchers have developed LA to treat it.

Wong et al. (1995) applied a gallium aluminium arsenide (GaAlAs) on 35 patients with CTS or repetitive stress injury. In their study, the output power was 100 mW. During a period of 8.2 months, every patient received 10 treatments. Each treatment involved the application of the laser probe perpendicularly to the tips of the spinous processes between

C5 and T1 for two to five minutes per point. The results showed that the disease had been successfully managed using LLLT.

Weintraub (1997) proved that LLLT could improve the condition of patients with CTS. He applied gallium aluminium arsenide (GaAlAs) continuous laser (wavelength 830 nm, output power 30 mW) perpendicularly at 33-second intervals to five points along the median nerve delivering a laser energy density of 9 J/point. It was a non-controlled test. Fifteen treatments were scheduled but were cancelled if patients became asymptomatic. The treatment energy density was a maximum of 74.25 J.

Branco et al. (1997) used laser light to stimulate the relative acupuncture points on patients suffering purely from CTS. They used a combination of transcutaneous electrical nerve stimulation (TENS) and other alternative therapies.

2.3.7 Outcome Measurements

Pain is a very important factor to CTS. Evaluation of relief pain in this case can indicate the degree of the patient's improvement. Some of the main methods of assessing pain are listed below, which are applied in this study:

Subjective Evaluations

Subjective evaluations included the McGill pain questionnaire and the VAS for evaluating a patient's subjective feedback. A review of the literature relating to these two methods was given above.

Objective Examination

A. Physical Examination --- Phalen's Test

For patients with CTS, one of the physical examination can be the Phalen's test, which is a special test for CTS. The patient holds his or her forearms vertically and completely flexes both hands at the wrist for about 60 seconds. In order to maintain this position, the median nerve is compressed between the transverse carpal ligament and the adjacent flexor tendons and the patient will complain of pain within 60 seconds. Following improvement of the condition, the patient will be able to keep this position without pain for a

longer period of time. Observing exactly how long will help to assess the degree of attenuation of the pain.

B. Kinesiological Properties Tests

For a patient who is suffering from pain, certain movements can aggravate the pain on the affected area of his or her body. Therefore, to assess the kinesiological function of the hand for patients with CTS may become a method to evaluate the effect of LA. In this study, there were two measurements used to monitor the kinesiological function of the hand: the grip strength test and the pinch strength test.

Mathiowetz et al. showed that the reliability and validity of grip and pinch strength evaluations made them suitable for assessing the improvement or comparing the effectiveness of various surgical or treatment procedures (Mathiowetz et al., 1984).

C. Nerve Conduction Studies

Because nerve conduction studies were an important part of this study, the methods are described in detail in the following section.

2.4 Nerve Conduction Studies

2.4.1 Introduction

Nerve conduction is a basic function of a nerve. Observing and recording the change of nerve conduction can reflect the functional change of the nerve. Nerve conduction studies consist of many factors, among which measuring the latency and calculating the nerve conduction velocity are most common.

For CTS, NCSs are considered as a primary definite diagnostic test. Observing the improvement of median nerve conduction allows an assessment of the degree of success of a CTS treatment.

The median nerve is a fixed nerve that is formed by sensory nerve fibre and motor nerve fibre. Figure 2.3 shows the anatomy of the median nerve. In this study, both latencies of sensory nerve conduction (SNC) and motor nerve conduction (MNC) will be measured and both velocities will be compared before and after the LA therapy.

Figure 2.4 and Figure 2.5 show the procedure for measuring MCV. Compound muscle action potential recorded from the thenar eminence after stimulation of the median nerve at the wrist and the elbow. The nerve conduction time from the elbow to the wrist equals the two responses elicited by the distal and proximal stimulation. The motor nerve conduction velocity (MNCV), calculated by dividing the surface distance between the stimulus points by the subtracted times, is concerned with the fastest fibres (Kimura, 1989). Figure 2.6 shows the standard waveform of MNC.

Figure 2.7 shows the stimulation procedure of sensory nerve conduction velocity on the median nerve. Antidromic surface stimulation is performed at the wrist between the palmaris longus and the flexor carpi radialis tendons, at the second distal-most crease. Ra refers to the active ring electrode that was placed around the proximal interphalangeal join of the second digit. Rr refers to the reference electrode around the distal phalanx of the same digit. Gd means ground electrode, which was placed over the dorsum of the hand (Liveson et al., 1992). Figure 2.8 shows the sensory conduction studies and Figure 2.9 shows the standard SNC waveform.

2.4.2 Effects of Laser Treatment on Nerve Conduction Studies

Research papers addressing the effects of LLLT on nerve conduction are rather few in number. In 1988, Snyder-Mackler et al. (1988) reported a significant increase in latency (μ = 0.37 msec, σ = 0.16 msec) on the peripheral sensory nerve. They used He-Ne laser delivering continuous energy at 19 mJ/cm^2 on six points along a superficial radial nerve. The test was a double-blind study. In 1993, Basford et al. (1993) reported that median nerve motor and sensory distal latencies decreased significantly ($p < 0.016$ and $p < 0.046$, respectively). They applied 830 nm continuous wave laser diode irradiation on normal subjects and 1.2 J/point. In 1994, Lowe et al. (1994) also used 830 nm energy density 1.5-12 J/cm^2 continuous laser light on the median nerve. They attested that especially at 1.5 J/cm^2 there were significant increases in latency.

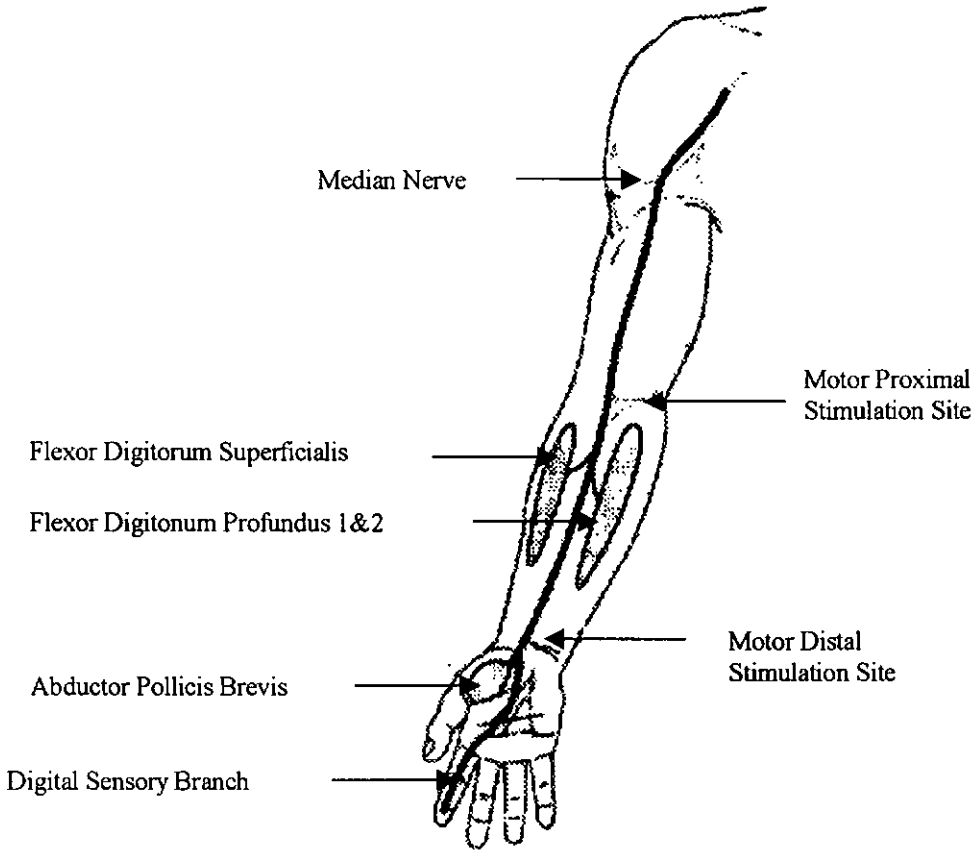

Figure 2.3. Scheme to show the anatomy of median nerve. (From Misulis, 1997)

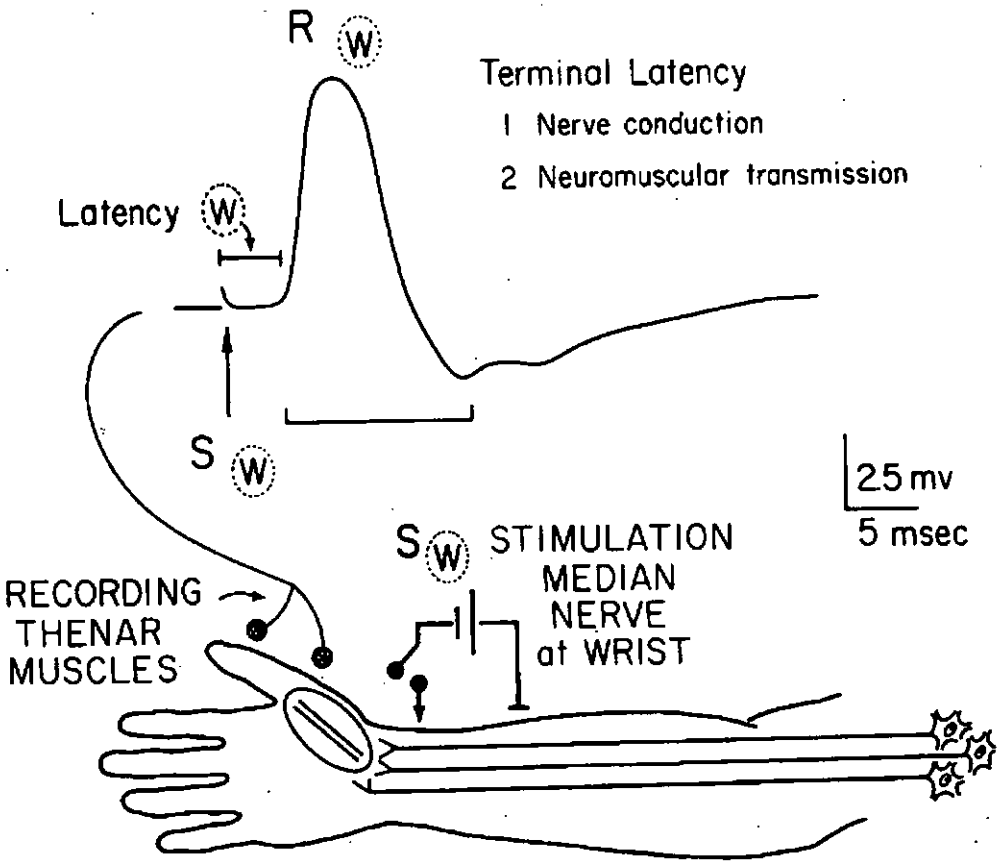

Figure 2.4. Compound muscle action potential recorded from the thenar eminence after stimulation of the median nerve at the wrist. (From Kimura, 1989)

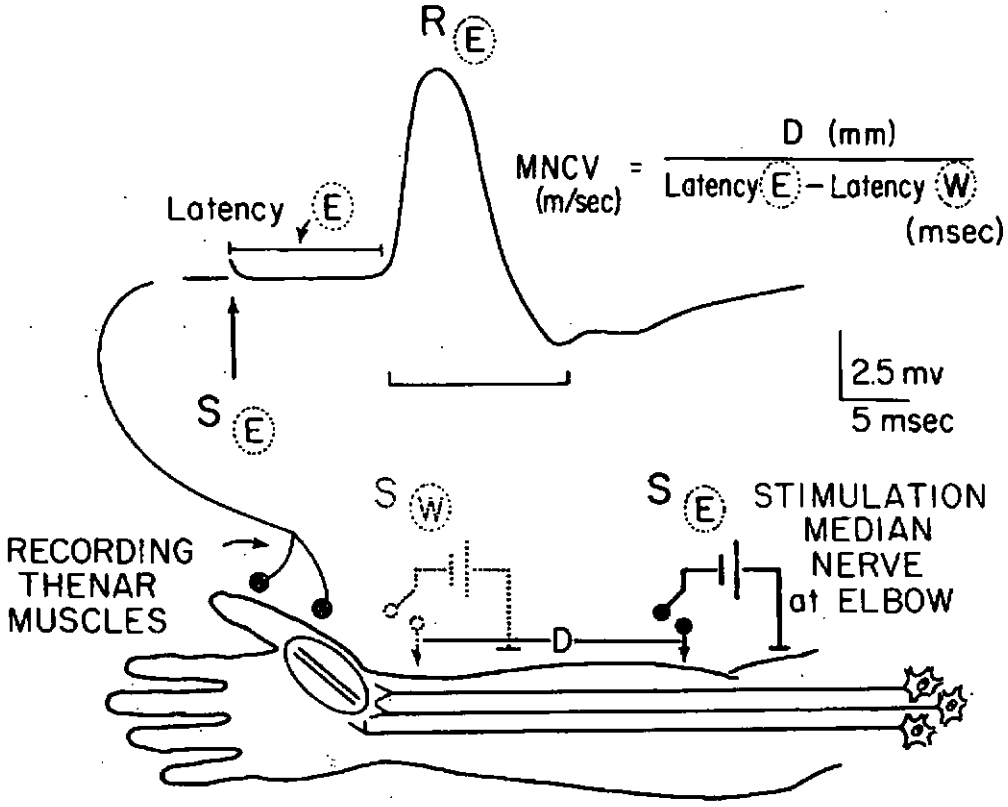

Figure 2.5. Compound muscle action potential recorded from the thenar eminence after stimulation of the median nerve at the elbow. (The nerve conduction time from the elbow to the wrist equals to the two responses elicited by the distal and proximal stimulation. The motor nerve conduction velocity (MNCV), calculated by dividing the surface distance between the stimulus points by the subtracted times, concerns the fastest fibers.). (From Kimura, 1989)

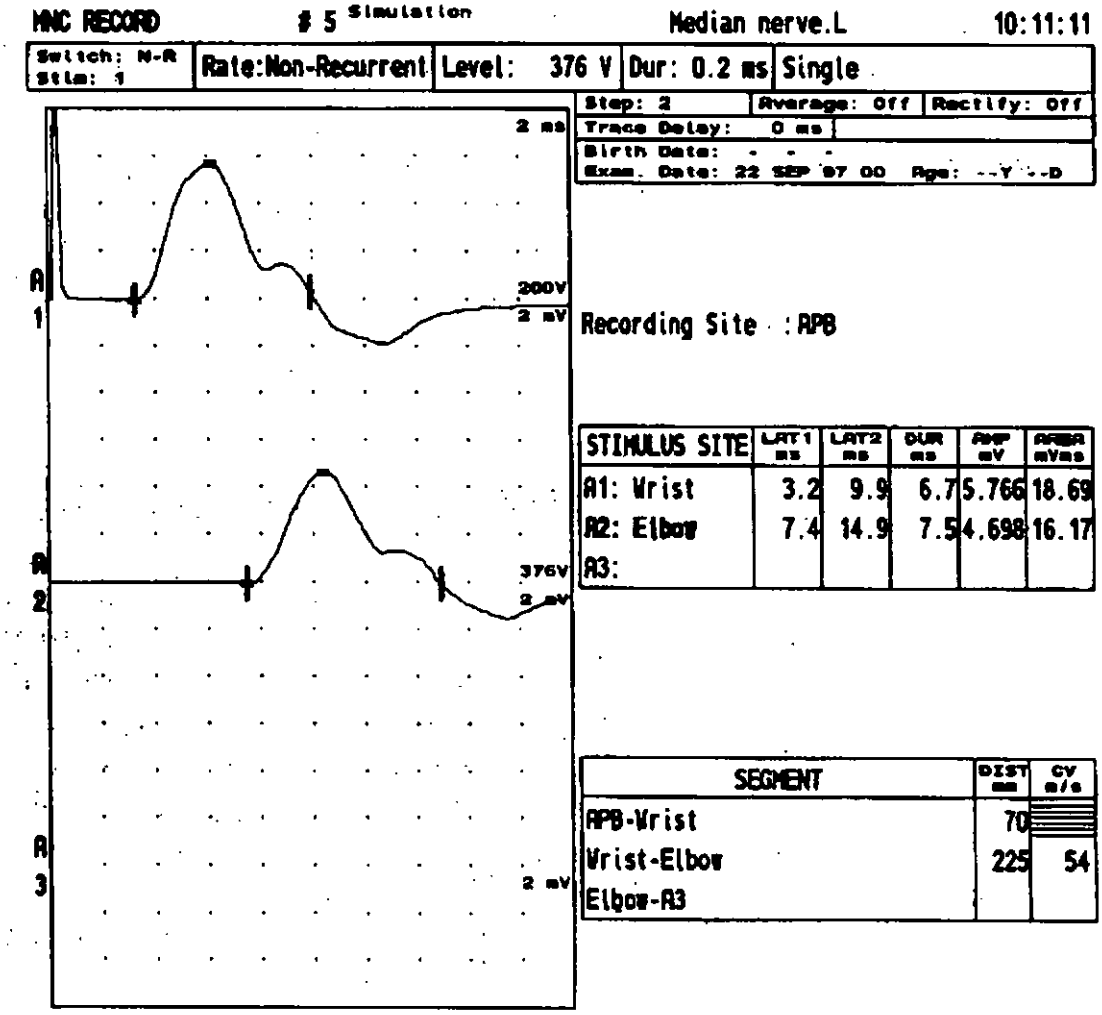

Figure 2.6. Compound muscle action potential (CMAP) of median nerve.

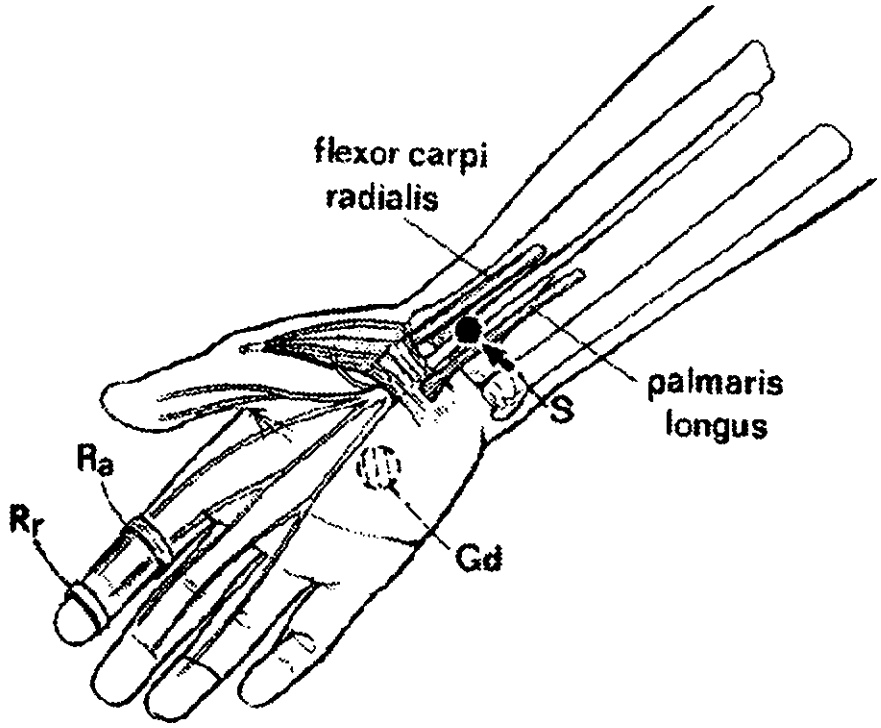

Figure 2.7. Stimulation procedure of sensory nerve conduction velocity on median nerve. Antidromic surface stimulation was performed at the wrist between the palmaris longus and the flexor carpi radialis tendons, at the second distal-most crease. Ra meant the active ring electrode, which was placed around the proximal interphalangeal join of the second digit. Rr meant reference electrode was around the distal phalanx of the same digit. Gd meant ground, which was placed over the dorsum of the hand. (From Liveson and Ma, 1992)

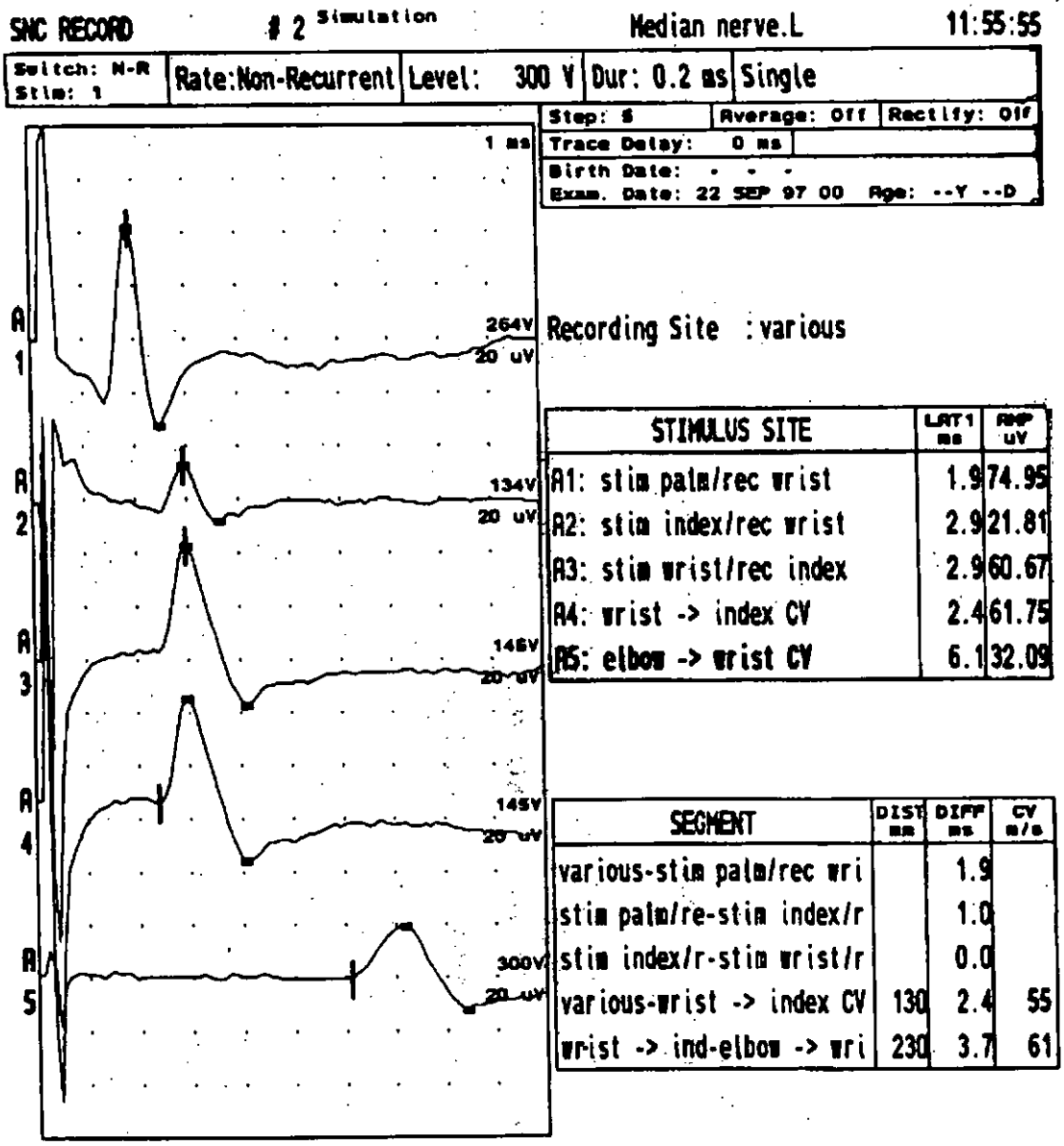

Figure 2.8. Sensory potential studies of median nerve.

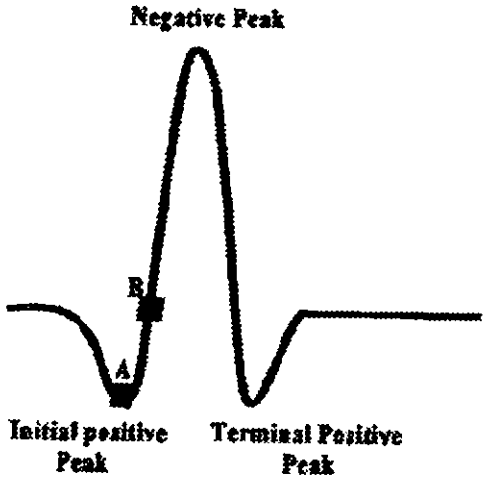

Figure 2.9. A sensory potential waveform.

Some researchers have noted a change of nerve conduction shortly after the patient was given laser irradiation. Fewer researchers, however, have observed the change of nerve conduction over time during the treatment stage. Besides, the amount of literature on this area is limited. It is necessary to do more research in the field using other forms of laser light and different therapeutic parameters.

2.4.3 Nerve Conduction Studies of Patients with Carpal Tunnel Syndrome

CTS can affect the median nerve conduction. After various conditions cause an increase in carpal tunnel content and result in nerve compression. If long-standing pressure in the tunnel is allowed to continue, disturbances in intraneural blood flow and axonal transport worsen, leading to permanent pathologic changes (Sunderland, 1976). Local relative ischemia and the resultant proteinaceous exudate promote fibroblast activity and proliferation. The final outcome is the destruction and replacement of the epineurium and endoneurium with dense fibrous scar tissue (Slater and Bynum, 1993). The result may be abnormal impulse generation and transmission, conduction delay, or complete nerve block (Ditmars, 1993). The earliest neurophysiological changes can be found in sensory conduction. Among them, an increased latency of the median nerve can be observed (Bhala et al., 1981). Following the aggravation of the symptom, the latency will increase until the

wave of sensory nerve conduction is absent and the motor nerve conduction has begun increasing its latency and decreasing its conduction velocity.

CHAPTER 3
EXPERIMENT—THE EFFECTS OF LASER ACUPUNCTURE ON NORMAL SUBJECTS

3.1 Objectives

In this study, an independent experiment to apply LA to normal subjects was conducted. Through investigating the changes of NCSs on normal subjects over time, the effects of LA for normal subjects were established. After exploring the objective changes of NCSs by LA, a correlative principle of relief pain by LA would be discussed. The main objectives included trying to see:

- Whether there is any significant change in NCV after LA treatment;
- Whether there is any significant change between pre-treatment and immediate post-treatment;
- Whether there is any significant change between pre-treatment and half an hour after LA treatment;
- Whether there is any significant change between immediate post-treatment and half an hour after LA treatment.

3.2 Methods

3.2.1 Selection of Subjects

Twenty healthy subjects were recruited from the Hong Kong Polytechnic University and screened for neuromuscular disorders. These normal subjects were recruited based on the following inclusion and exclusion criteria:

- aged between 20 and 40 years;
- no previous history of peripheral nerve system problem;
- no previous history of injury to upper extremities;
- no previous history of LLLT or LA;
- no current uncomfortable syndrome;
- no medications, massage, or therapy having been received during the previous month;

- not suffering from any other disease;
- not pregnant.

Further, all subjects were required to pass twice nerve conduction measurement examinations of their bilateral median nerves. A subject would be excluded if he or she did not meet the conditions that complied with the criteria of the normal median nerve conduction range. Detailed data is given in Table 3.1.

3.2.2 Experimental Design

In this study, a controlled experiment was established. The left upper extremities of all normal subjects were applied with LA, while the corresponding right sides were not applied with LA, which was the controlled condition.

Before the LA was applied, two separate NCV measurements were performed on different days in order to define the baseline of NCV, which described the original status of the median nerve. This was followed by a 10-day continuous LA application. During this period, the NCV was measured on the first, fifth, and tenth day to observe the potential serial changes over time. On each day, the NCV was recorded twice after the LA application. The first measurement was made immediately after finishing LA. The second was conducted after 30 minutes making it became possible to estimate the NCV changes caused by LA over the short term.

3.2.3 Instruments

Laser Therapy Unit

A laser therapy unit (model DDII THOR, UK) connected with a single-diode visible-red laser probe was used for treatment in this study (Figure 3.1). It is widely and beneficially used in both hospitals and private practices in other countries.

The safety classification of low-level laser light, which emitted by this equipment, was 3B. That meant it was safe to use but potentially hazardous if the beam or specular reflections were directly viewed (Baxter, 1994; Sliney et al., 1993). In order to reduce the possibility of injuring the eyes, the nominal ocular hazard distance was 25 cm, which was a

Table 3.1. Normal data range for previous studies of median nerve conductions (Campbell, 1999; Misulis, 1997)

NCV	MNCV	Anti-SNCV	Ortho-SNCV
Active electrode site (G1)	APB	Index	Wrist crease
Reference electrode site (G2)	Tendon	3cm distal to G1	3cm proximal to G1
Stimulation site	Wrist	Wrist	Index
Proximal stimulation site 1	Elbow	-	-
Amplitude	> 3mV	> 15μV	> 5μV
Distal latency (ms)	< 4.5	< 3.7	< 3.7
CV (m/s)	> 50	≥ 55	≥ 55

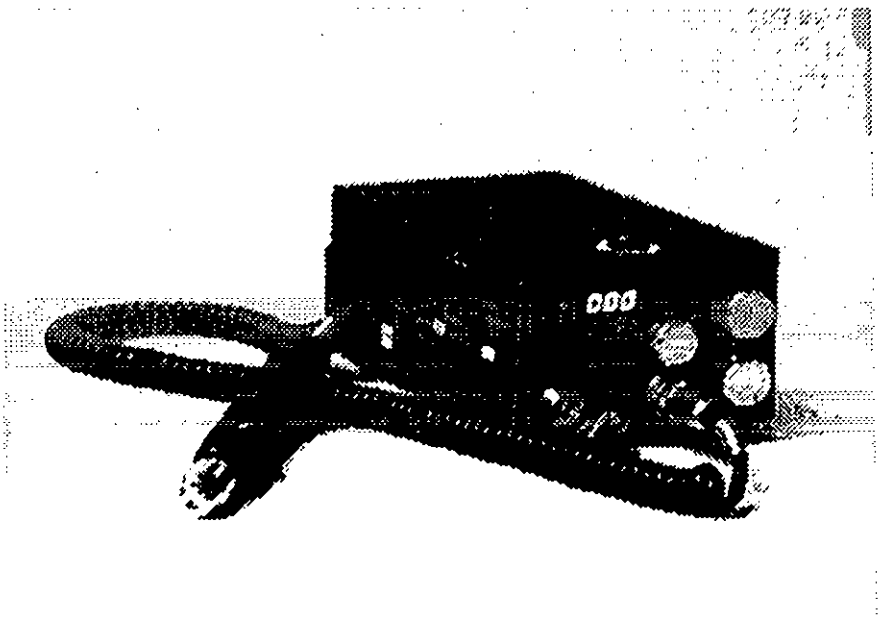

Figure 3.1. The laser therapy unit (model DDII, THOR, UK) connected with a single-diode visible-red laser probe.

special function of the laser therapy unit used in the current experiment. This meant that if the distance between the eyes and the probe was more than 25 cm when the eyes accidentally were irradiated directly by the light beam, the laser light would not cause any damage because the output power of laser had been reduced to a level which did not cause injury. There were other, more important items to be noticed during LA manipulations carried out to avoid injuring the eyes. These were as follows:

- The LA therapy unit was turned on after the probe was properly put on the acupuncture point of the patient's body.
- During operation, the LA probe was held firmly by the operator in order to avoid accidentally moving it from the exact acupuncture point.
- The subject was advised not to move his or her upper extremity during the LA application.
- During the whole period of the LA operation, protective goggles were provided to both the operator and the patient.

In addition, there were also certain basic safety policies that contained guidelines for administrative control and environmental concern. These were as follows:

- A controlled area was designed as experimental area suitably marked with warning symbols (Figure 3.2).
- Only authorised and properly trained personnel should operate the laser equipment.
- The key should be removed from the key-switch master control at all times, except when the laser is in use. It must not be left in the equipment.
- The laser warning sign outside the door must be illuminated whenever laser operation is in progress.
- Direct laser radiation into the eyes or off a reflective surface must be avoided.

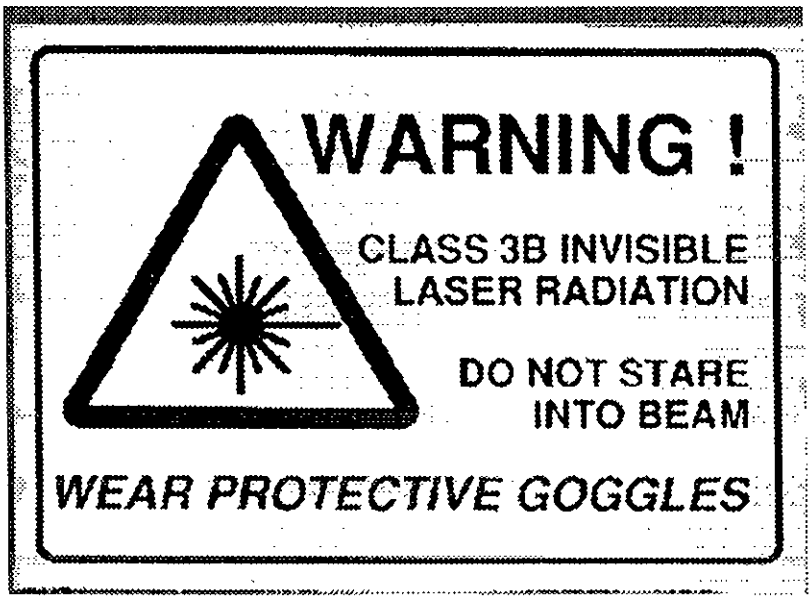

Figure 3.2. Warning symbol marked in the experimental area

Table 3.2. Specifications on the experimental parameters of laser therapy unit

Wavelength	680 nm
Mean output power (MOP)	30 mW
Peak power	33 mW
Spot size of light	0.28 cm^2
Type of laser light	Continuous wave
Average power density	107 mW/cm^2 (1.07 W/m^2)
Beam divergence	10° X 30°
NOHD*	25 cm

* NOHD means nominal ocular hazard distance.

The system parameters of the LA therapy unit are listed in Table 3.2 above. According to the specification from the manufacturer, the THOR-DDII Unit has an auto-calibration of 680nm wavelength. The accuracy of time and power for the stated wavelength is ±10%. The THOR-DD II has a built-in power meter with which it can accurately evaluate the output power of both LED and laser probes. This power meter has an automatic calibration feature.

Electro-diagnostic Unit

A Viking IV P electro-diagnostic system (Nicolet, U.S.) was used for nerve conduction studies in the experiment (Figure 3.3).

Besides basic issues with maintenance, data recording and serving, a strict safety program for the operation of the unit was established. The program was designed according to the electro-diagnostic unit's manual and basic safety regulation's of nerve conduction studies.

- A controlled area should be designed as the experimental area and the system should be locked within this area.

- Only authorised and properly trained personnel should operate the electro-diagnostic system.
- To reduce the risk of injury, all recording and stimulating electrodes should be disconnected from the system before the operator turns the system power off or on.
- Before use, the operator must check that all cables are connected properly and verify that all functions of the system run properly.
- Before giving electric stimulation to the subject, the operator must check again that the electric stimulus value is correct.
- The patient's skin should be kept clean, dry, and free of excessive conductive gel.
- Nerve conduction studies must not be performed on a subject with an external conductive lead terminating in or near the heart.
- The stimulus intensity should be chosen from small values according to the different tolerance level of the subjects. For normal subjects, a surface stimulation of 5 to 40 mA is usually applied; for patient subjects, a maximal output of 60 to 75 mA is often used (Kimura, 1989).

During the experiment, nerve conduction velocities were measured by this electro-diagnostic system. These nerve conduction velocities included motor nerve conduction velocity (MNCV), antidromic sensory nerve conduction velocity (anti-SNCV), and orthodromic sensory nerve conduction velocity (ortho-SNCV). For the purposes of measuring these nerve conduction velocities, system parameters were chosen. These are described in Table 3.3.

On the control panel of the electro-diagnostic system, there was a Calibrate key that could turns the amplifier calibration pulse ON and OFF. The Nicolet Viking IV automatically adjusted the amplitude and frequency of the calibration pulses based on system sensitivity and timebase settings. The calibration pulses in all test modes are system checks and a data source for self-instruction. Based on auto scaling the calibration function of this system, the Calibrate key should be turn the pulse ON once in order to set a proper programmer for measurement.

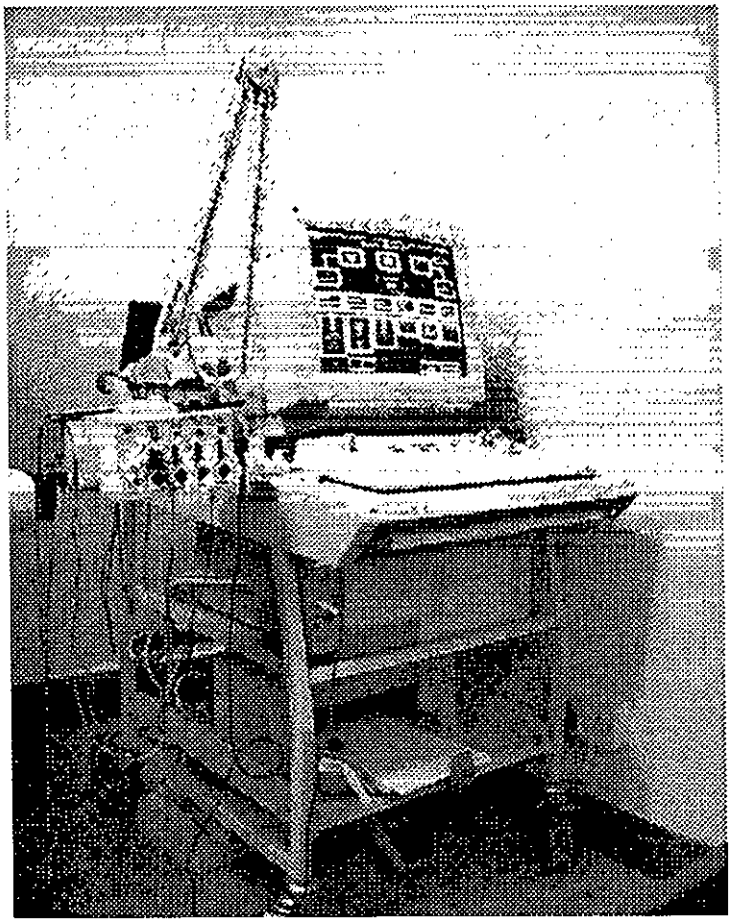

Figure 3.3. Viking IV P electro-diagnostic system (Nicolet, U.S.) used for nerve conduction studies.

Table 3.3. Specifications on the experimental parameters of the electro-diagnostic system

Parameter	MNCV	SNCV
Gain	2 mV/division	20 μV/division
Time base	2 ms/division	1 ms/division
LFF*	10 Hz	10 Hz
HFF**	32 kHz	2 kHz
Stimulus duration	0.2 ms	0.1 ms

* LFF means the setting of the low frequency filter.

** HFF means the setting of the high frequency filter.

3.2.4 Procedure

The experimental area was of a purpose built design. Within the area, a warning symbol about laser safety was posted in a conspicuous place. Room temperature was maintained at 23-24°C (Kimura, 1989). This was achieved by an air conditioner and a thermometer that was hung in the experimental area to monitor air temperature at all times.

The objectives and the detailed experimental procedures of the study were explained to the subjects. In particular, the subjects were told about the possibility that some pain or slight discomfort would be felt during the nerve conduction studies, and that they had the right to withdraw from the study at any time without giving a reason. If the subject agreed to participate in the study, a consent agreement was signed (Appendix I). Then information about the subject was collected, including weight, height, age, gender, and health history.

The subject sat with arm supported on a suitable table. Before LA treatment, skin preparation was necessary. The skin of each acupuncture point was wiped with alcohol to help keep a clean skin surface.

LA was applied for three minutes per point on four acupuncture points on the left upper extremity of each subject for each day over a ten-day period. These acupuncture points included PC6, PC7, PC8, and LI4 (Figure 3.4), which were chosen according to the principle of Traditional Chinese Medicine. They were named based on standard international nomenclature (Appendix II) (World Health Organization, 1990). The location and function of each acupuncture point (with the Pinyin name of traditional Chinese medicine in parentheses) are described below. The criteria for selecting acupuncture points' locations were based on anatomical landmarks, bone-length measurement (cun is the unit in Traditional Chinese Medicine, that means the width of the interphalangeal joint of the subject's thumb), and finger measurement (this refers to the length and width of the patients' fingers are taken as a standard for point location).

PC 6 (Neiguan) was 2 cun above the transverse crease of the wrist, between the tendons of the muscle palmaris longus and the muscle flexor radialis.

PC 7 (Daling) was in the middle of the transverse crease of the wrist, between the tendons of the muscle palmaris longus and the muscle flexor carpi radialis.

PC 8 (Laogong) was between the second and third metacarpal bones. When the fist was clenched, the point was just under the tip of the middle finger.

LI 4 (Hegu) was on the dorsum of the hand, between the first and second metacarpal bones, in the middle of the second metacarpal bone on the radial side.

The laser probe was placed directly on the subject's skin of the respective acupuncture point in perpendicular direction while the palm of the subject was put horizontally up or down on the table. Figure 3.5 shows the manipulation of LA. Before and after each LA application, the subject was asked to rest for 20 minutes.

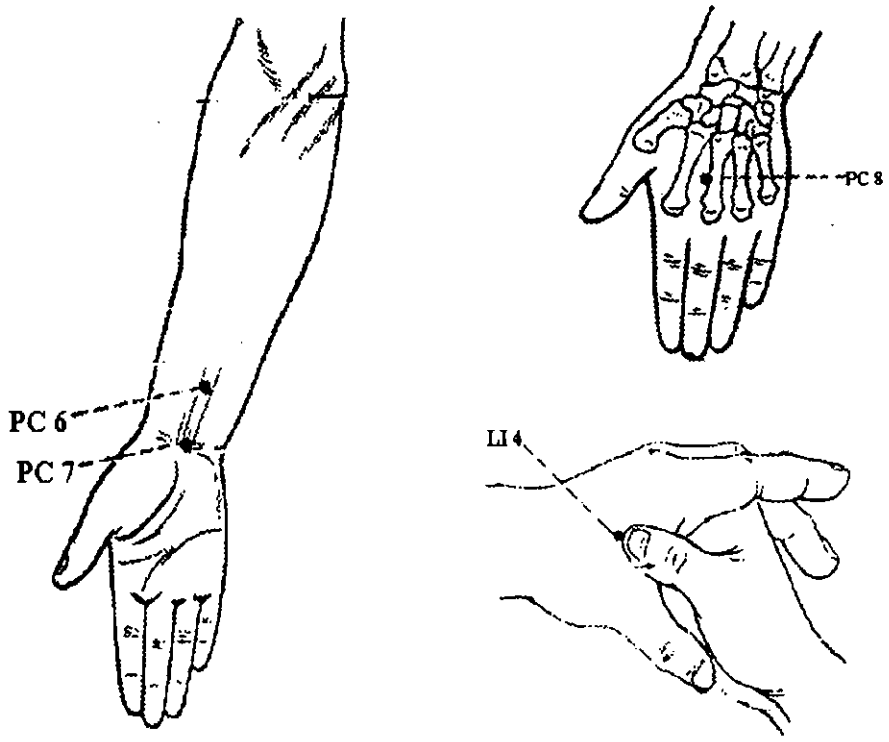

Figure 3.4. Diagram of LI4, PC6, PC7, and PC8 point locations.

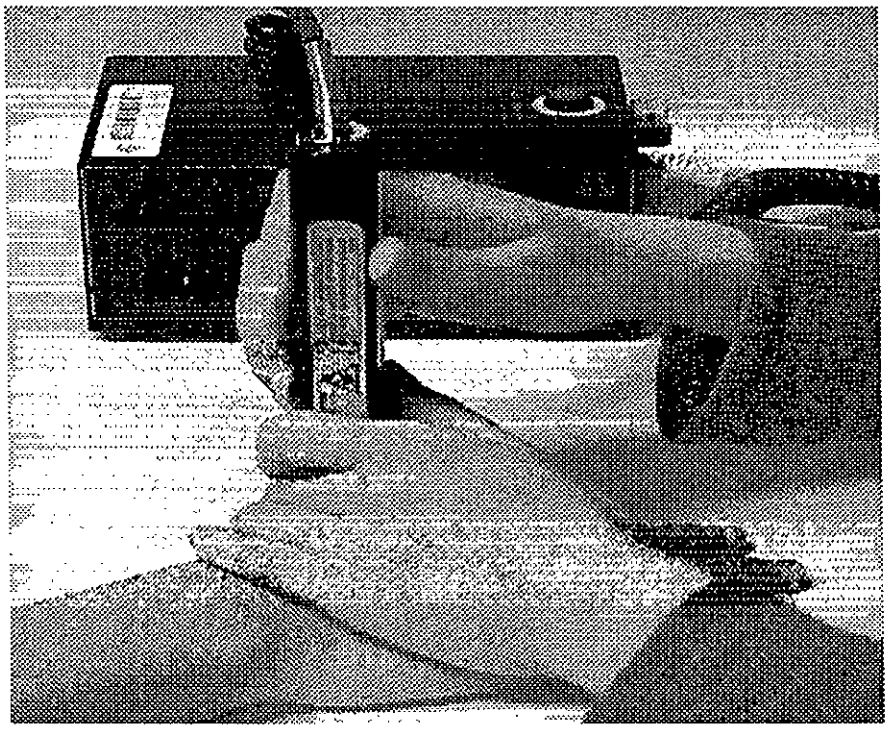

Figure 3.5. LA experimental setup.

3.2.5 Evaluations

NCSs were studied in the experiment as evaluations for the effects caused by LA treatment. Nerve conduction velocities of the bilateral median nerve were measured once on the day before the first day of LA applications. During the following day, NCV was taken once at the pre-laser period and twice at the post-laser period. On the fifth and tenth days, NCV was taken twice at the post-laser period. The interval between nerve conduction velocity measurements at the post-laser period was 30 minutes.

Before measuring the nerve conduction velocities, adequate skin preparation for the stimulating and recording sites was very important to reduce the skin resistance. An abrasive skin gel (NuprepTM, U.S.) was applied to the electrode site on the scalp by rubbed lightly with a cotton swab. The residue of the skin gel was wiped away and then alcohol was applied to help dry and clean the skin surface before the application of the stimulus.

Median nerve conduction studies were performed on both upper extremities to investigate the effect of LA on nerve conduction velocities. The measurements included

motor nerve conduction velocity (MNCV) and sensory nerve conduction velocity (SNCV). The measurements of SNCV included antidromic SNCV (anti-SNCV) and orthodromic SNCV (ortho-SNCV).

Motor Nerve Conduction Test

Figure 3.6 shows the procedure of measuring MNCV. For the motor conduction studies in the study, the median nerve was stimulated at the wrist and elbow two points along its course. A bar stimulating electrode (including both an anode and a cathode with the anode 2cm proximal to the cathode) was placed on the skin of the wrist, 3 cm proximal to the distal crease of the wrist and on the skin of the elbow nearly at the point of the pulse of the artery of brachiali that gave an electric stimulus. A pair of surface electrodes was used as recording electrodes: an active lead (G1) was placed on the belly of the abductor pollicis brevis muscle and an indifferent lead (G2) was placed on the tendon (belly-tendon recording). The ground was attached to the same limb between the stimulating electrode and the recording electrodes.

Pulses of moderate intensity were used first to adjust the position of the cathode until further relocation caused no change in the size of the muscle action potential. With the cathode at the best stimulating site, one then defined the maximal intensity that just elicited a maximal potential. Increasing the stimulus further should result in no change in the size of the muscle potential. Usually, supramaximal stimulus, which was 20-30% more than moderate intensity, was used to guarantee the activation of all the nerve axons innervating the recorded muscle.

Finally, the value of the distance between the two stimulating cathodes was recorded and input to the Viking electro-diagnostic system. Based on the recorded waveforms of motor action potentials, the proximal latency and distal latency were recorded in the system. Furthermore, the MNCV was calculated according to the following formula:

$$\text{MNCV} = \frac{Dist}{PL - DL},$$

where PL was the proximal latency, DL was the distal latency, and Dist was the distance between the stimulating cathodes. Latencies were measured in ms and distance in

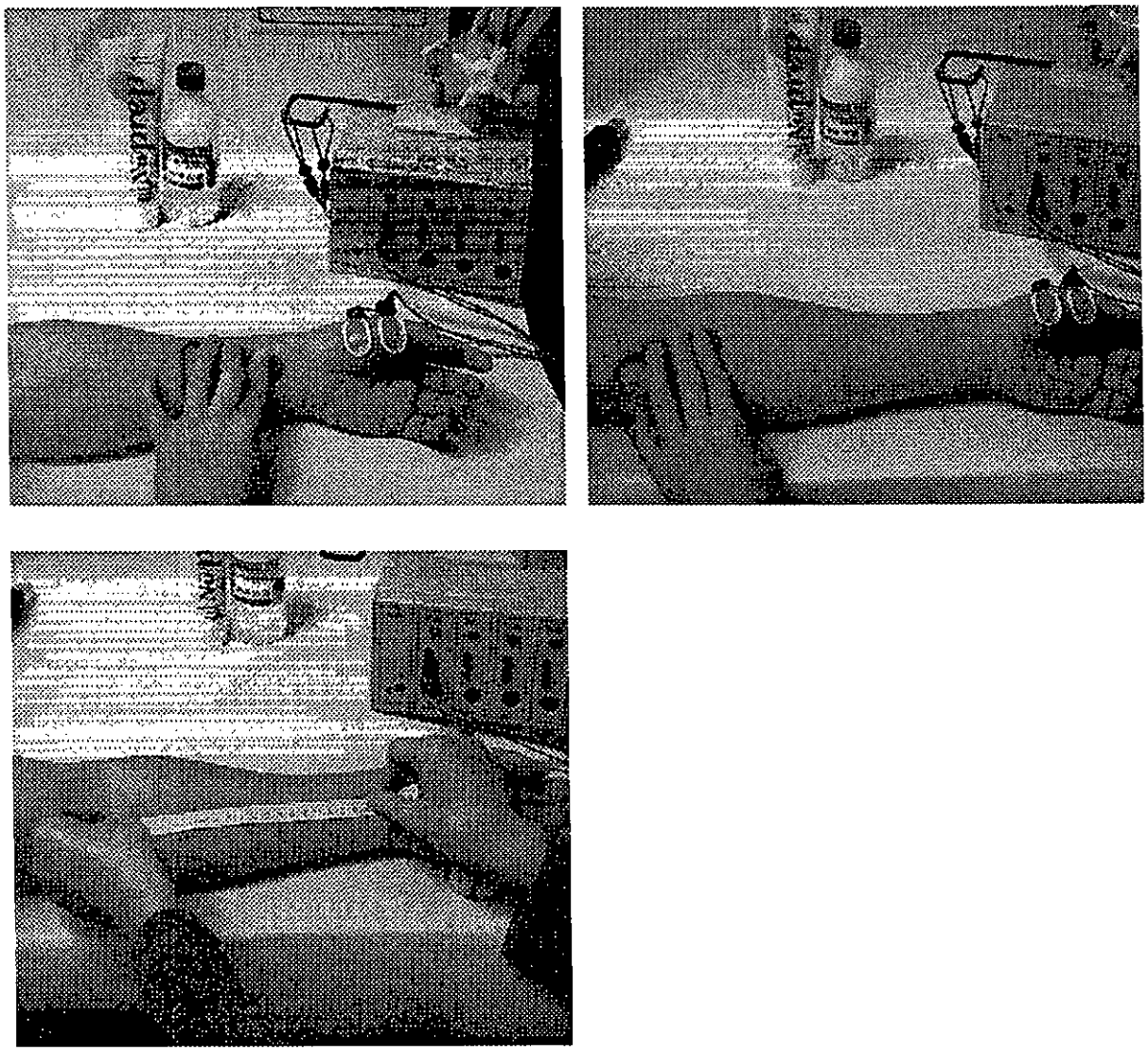

Figure 3.6. Measurement of motor nerve conduction velocity.

mm. The final results of MNCV were expressed as m/s. Comparing the changes of MNCV was a way of evaluating the effects of LA treatment.

Sensory Nerve Conduction Test

Sensory nerve conduction velocities were measured more directly than MNCV. Only one stimulating site was needed, because sensory conduction studies did not encounter the delay of neuromuscular transmission seen with motor studies. The stimulating and recording were directly to and from the sensory nerve. SNCV could be performed with activation in the normal direction of action potential propagation (orthodromic stimulation) or in the reverse direction (antidromic stimulation). Both sensory nerve conduction velocities were measured in the study, because there should be a slight discrepancy in the NCV calculated from the two methods due to differences in geometry of volume conduction.

Figure 3.7 shows the procedure for measuring Ortho-SNCV. Ortho-SNCV was measured by stimulating distally and recording proximally in the direction of normal impulse flow. A pair of ring electrodes were used as stimulating electrodes: an active lead (G1) was placed around proximal interphalangeal joints of the index finger and an indifferent lead (G2) was placed around distal interphalangeal joints of the index finger with a 2cm interval between them. Two surface electrodes were placed at the wrist over the course of the median nerve and there was a distance of 2 cm between the two centres of these surface electrodes. The ground was attached on the same limb between the stimulating electrode and the recording electrodes.

Figure 3.8 shows the procedure for measuring Anti-SNCV. Stimulating proximally and recording the retrogradely transmitted potential distally measured anti-SNCV. A bar electrode (including both an anode and a cathode with the anode 2 cm proximal to the cathode) was placed on the wrist over the course of the median nerve as the stimulating electrode. Two surface electrodes were used as recording electrodes: an active lead (G1) was placed on distal interphalangeal joints of the index finger and an indifferent lead (G2) was placed on proximal interphalangeal joints of the index finger with a 2 cm interval between their centre points. The ground was attached to the same limb between the stimulating electrode and the recording electrodes.

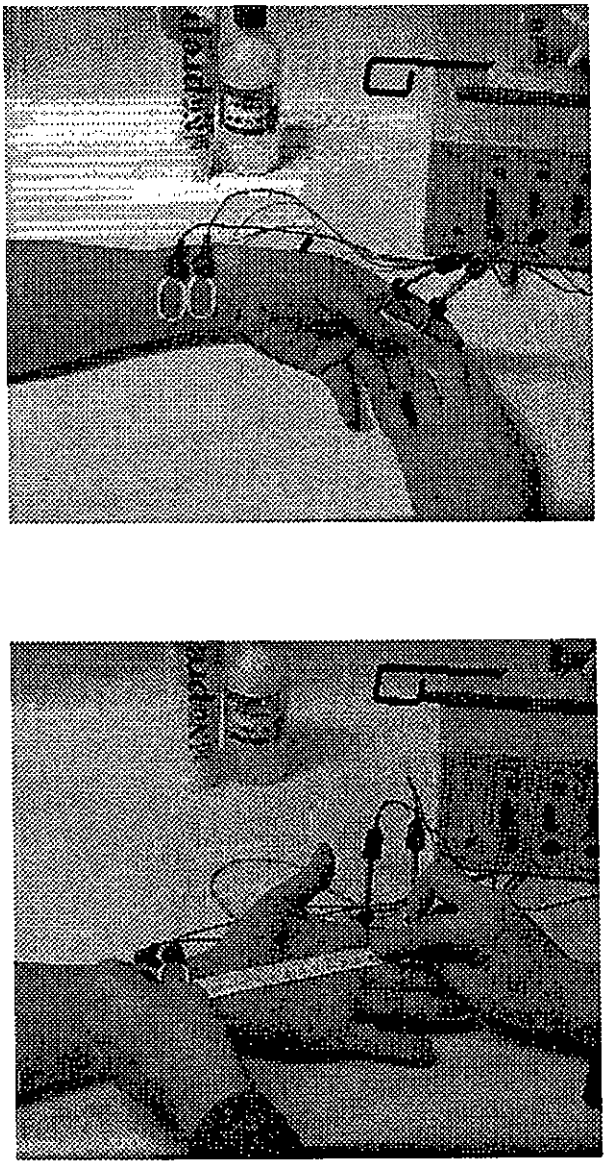

Figure 3.7. Measurement of orthodromic sensory nerve conduction velocity.

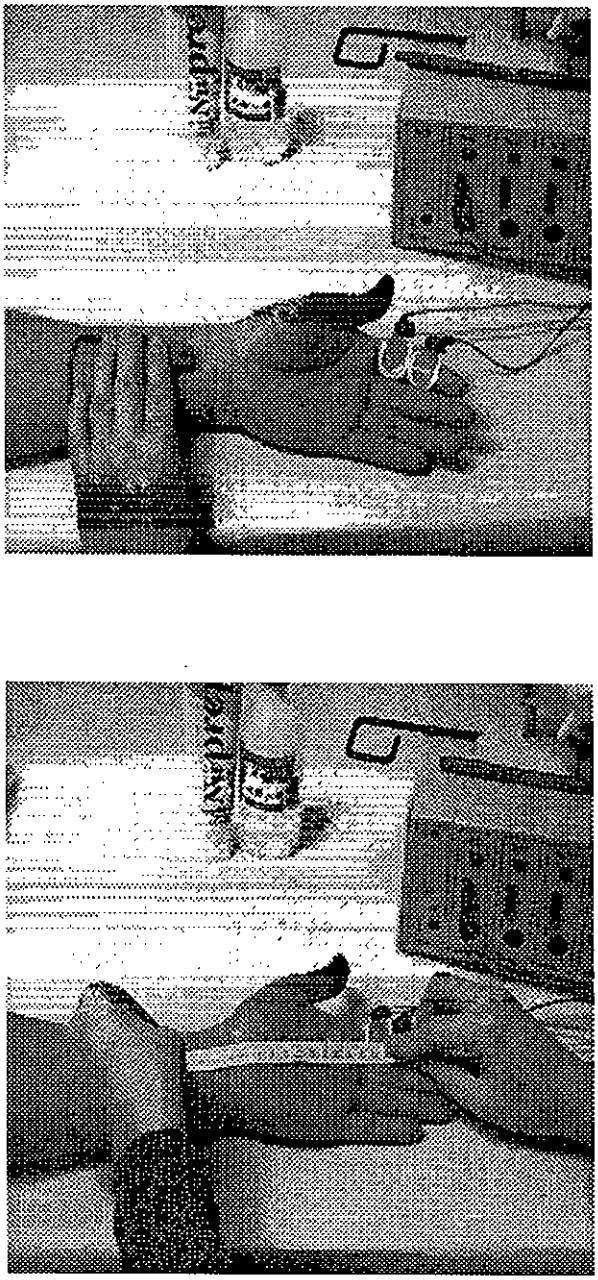

Figure 3.8. Measurement of antidromic sensory nerve conduction velocity.

During the SNCV measurement, the distance between the stimulating cathode and the active recording electrode was recorded and input to the electro-diagnostic system. According to the recorded waveforms of sensory nerve action potential, the latency of takeoff was recorded. Further, the SNCV was calculated according to the following formula:

$$\text{SNCV} = \frac{Dist}{LT},$$

where Dist was the distance between the stimulating cathode and active recording electrode, and LT was the latency to takeoff of the potential. The final results of SNCV were expressed as m/s too. Comparing the changes of SNCV was a way of evaluating the effects of LA treatment.

3.3 Results

3.3.1 Statistical Analysis

Firstly, a descriptive statistical method was used to describe the basic characteristics of the subjects.

Secondly, for all outcome measurements, means and standard deviations (SD) were calculated. All experimental values of the nerve conduction test were listed to the placebo and the LA group. Paired-samples t-test was used for correlation measure to analyse the intra-group changes. In addition, one nonparametric method—a Wilcoxon signed rank sum test—was used to confirm the results from the t-test. All of the mentioned statistical tests were computerized by SPSS (10.0). A value of $p < 0.05$ was considered significant for every statistic result.

3.3.2 Subjects' Demographic Characteristics

Twenty normal subjects were recruited voluntarily and eighteen finished the experiment. The rest two subjects withdrew from the experiment because they could not receive the LA treatment continuously for the ten-day period for their private time schedule. Totally, thirty hands were studied (12 hands in the placebo group and 18 hands in the LA group; during the early period of the experiment, for first 6 subjects, only one hand was treated by LA while the other hand was not treated as controlled hand) finished the test.

These subjects included 11 males and seven females, aged from 23 to 40 years (mean 31.12 years, SD 3.87). The age distribution of the normal subjects is shown in Table 3.4. Results showed that 28% were from 20 to 29, 67% were from 30 to 39, and 5% were from 40 to 49. The gender distribution of the normal subjects is shown in Table 3.5.

Table 3.4. Frequency distribution of subject ages

Age range (year)	Frequency	Percentage
20-29	5	28%
30-39	12	67%
40-49	1	5%
Total	18	100%

Table 3.5. Frequency distribution of subject genders

Gender	Frequency	Percentage
Male	11	61%
Female	7	39%
Total	18	100%

3.3.3 Electro-diagnostic Findings

To investigate the effects of LA on normal subjects, there were three electro-diagnostic evaluations. According to the three types of experimental data, there were several means forming relationships. These averages included below,

- the pre-treatment velocity which presented the average from measuring nerve conduction measurements twice before the beginning of the laser therapy (the first time was

during the day before the first day of LA applications, and the second time was during the first day just before the start of the laser therapy);

- the average of all nerve conduction velocity values taken after the beginning of LA application (marked as post-treatment);
- the average of all values taken immediately after LA on the first, fifth, and tenth days (marked as post-0);
- the average of all values taken 30 minutes after every LA application on the first, fifth, and tenth days (marked as post-30);
- the value measured after 30 minutes on the tenth day was regarded as the final parameter after the whole experiment had ended (marked as the final baseline).

Table 3.6 shows the descriptive statistics of NCV on normal subjects, which include the mean and the SD for MNCV, An-SNCV, and Or-SNCV in both the placebo group and the LA group.

A paired-samples t-test was used separately to determine whether differences existed in either the placebo group or the LA group between pre-treatment and post-treatment, pre-treatment and post-0, pre-treatment and post-30, post-0 and post-30, and pre-treatment and the final value after the last treatment. The results are shown in Table 3.7. According to the MNCV test, the results show that the LA group had very significant changes ($p < 0.001$) for five hypothesis tests. Specifically, the velocities, including the post-treatment velocity, post-0 velocity, post-30 velocity, and the velocity measured after the whole experiment was finished, decreased significantly due to LA treatment. Further, there was a significant difference between post-0 and post-30 ($p < 0.001$), which suggested that the effect of LA was stronger 30 minutes after the LA operation than immediately after the LA operation. In the table, it was obvious that all values at different periods in the placebo group changed insignificantly ($p > 0.05$).

The same statistical procedure was used for anti-SNCV data. The results in the LA Group have a similar meaning to those of the MNCV data. Only the value of p for the difference between the pre-treatment and the post-0 velocity was 0.009, but it was still smaller than 0.05. In placebo group, for the five hypothesis tests, there were three insignificant differences. The results of ortho-SNCV show that in the LA group there were

Table 3.6. Descriptive statistics of NCV on normal subjects (Unit: m/s)

	Placebo group (n = 12)			LA group (n = 18)		
	MNCV	Anti-SNCV	Ortho-SNCV	MNCV	Anti-SNCV	Ortho-SNCV
Pre-treatment	57.73 ± 3.09	59.91 ± 3.13	58.47 ± 3.18	59.84 ± 3.36	59.66 ± 3.58	58.93 ± 3.02
Post-treatment	57.54 ± 3.04	59.05 ± 3.02	58.04 ± 2.87	55.50 ± 2.69	57.22 ± 3.60	56.75 ± 3.17
Post-0	57.53 ± 3.15	59.32 ± 2.98	58.32 ± 2.80	56.31 ± 2.80	58.23 ± 3.64	57.54 ± 3.00
Post-30	57.56 ± 2.95	58.78 ± 3.23	57.77 ± 3.00	54.69 ± 2.63	56.42 ± 3.77	55.96 ± 3.52
Final baseline	57.92 ± 3.15	59.25 ± 2.56	57.83 ± 3.59	55.33 ± 2.83	56.17 ± 4.23	55.72 ± 3.94

Table 3.7. Summary of statistical results of NCV on normal subjects by paired-samples *t*-test

Paired-samples *t*-test		Placebo group (n = 12)	LA group (n = 18)
		p	*p*
MNCV	Pre-treatment and post-treatment	0.244	0.000*
	Pre-treatment and post-0	0.328	0.000*
	Pre-treatment and post-30	0.274	0.000*
	Post-0 and post-30	0.880	0.000*
	Pre-treatment and final-treatment	0.369	0.000*
Anti-SNCV	Pre-treatment and post-treatment	0.014	0.000*
	Pre-treatment and post-0	0.119	0.009*
	Pre-treatment and post-30	0.013	0.000*
	Post-0 and post-30	0.239	0.000*
	Pre-treatment and final-treatment	0.076	0.000*
Ortho-SNCV	Pre-treatment and post-treatment	0.251	0.001*
	Pre-treatment and post-0	0.697	0.027
	Pre-treatment and post-30	0.086	0.000*
	Post-0 and post-30	0.040	0.001*
	Pre-treatment and final-treatment	0.154	0.000*

Table 3.8. Summary of statistical results of NCV on normal subjects by Wilcoxon signed-ranks test

Wilcoxon signed-ranks test		Placebo group (n = 12)	LA group (n = 18)
		p	*p*
MNCV	Pre-treatment and post-treatment	0.308	0.000*
	Pre-treatment and post-0	0.374	0.000*
	Pre-treatment and post-30	0.289	0.000*
	Post-0 and post-30	0.929	0.000*
	Pre-treatment and final-treatment	0.286	0.000*
Anti-SNCV	Pre-treatment and post-treatment	0.028	0.001*
	Pre-treatment and post-0	0.155	0.007*
	Pre-treatment and post-30	0.019	0.000*
	Post-0 and post-30	0.530	0.002*
	Pre-treatment and final-treatment	0.060	0.001*
Ortho-SNCV	Pre-treatment and post-treatment	0.308	0.004*
	Pre-treatment and post-0	0.937	0.019*
	Pre-treatment and post-30	0.071	0.001*
	Post-0 and post-30	0.050	0.003*
	Pre-treatment and final-treatment	0.433	0.001*

very significant changes for four hypothesis tests ($p < 0.001$) but not for the comparison between pre-treatment velocity and post-0 velocity ($p = 0.027$). Anyway, it still meant that the immediate effect after LA application for ortho-SNCV was significant. Between pre-treatment and post-treatment, and between post-0 and post-30, there were very significant differences ($p < 0.001$) respectively, which indicated that the ortho-SNCV was affected over time by LA application. In the placebo group, all the values at different periods changed little ($p > 0.05$) except the change between post-0 and post-30 ($p = 0.040$).

In addition to the paired-samples t-test, a nonparametric test—the Wilcoxon signed-ranks test—was applied in order to make sure that the experimental data were from a normal distribution and confirm the results from the t-test. The results of the Wilcoxon tests are shown in Table 3.8. They all had similar meanings to the results from the paired-samples t-test. This not only supports the conclusion from the paired-samples t-test, but also indicates that the measured values of the experiment were a normal distribution.

3.4 Discussion

3.4.1 Discussion on the Experimental Design

Although designing a double-blind, placebo-controlled, and randomised study is a recent trend, it is generally considered as the "gold standard" (Naeser, 1997). The reason for setting up a double-blind, placebo-controlled, and randomised study is to reduce the degree of psychological effects. In this study, there is no subjective feedback to be collected. Only an objective magnitude of NCV is measured as the unique assessment. The relative parameters were collected objectively by the electro-diagnostic system. NCV could be affected by objective factors, which include, temperature, variation among different nerves and segments, the age of the subjects, ischemia, and so on, but the subjective factor was not included (Kimura, 1989). Therefore, it was practicable to ignore the subjective influence from normal subjects. Therefore, a simple controlled experiment was established in this study. The left upper extremity of each normal subject was applied with LA while the right was controlled. No sham LA application was performed on the right upper extremity. The results in the placebo group showed that only three parameters showed $p < 0.05$ while other

twelve parameters showed insignificant treatments. However, in LA group, all hypothesis tests prove that LA cause very significant effects ($p < 0.01$) except for only one ($p = 0.027$). It is very obvious that LA cause the significant changes of nerve conduction velocities. This indicated that establishing a controlled experiment for this study to replace a double-blind, placebo-controlled, and randomised study was practicable.

3.4.2 Laser Dosage

A review of previous studies reveals that Walker (1983) used 0.005 J/point, Snyer-Mackler et al. (1986) used 0.01 J/point, Wong et al. (1995) used 100 mW, and Kemmotsu (1998) used 150 mW and 60 mW for three minutes on human subjects. All of these studies suggest that a positive conclusion can be made regarding low-level laser therapy. This meant that the laser dosage used was in the proper range according to the Arndt-Schultz law.

Certain factors were considered when deciding what laser dosage to use. These factors included the cumulative dose, the number of acupuncture points, the actual time for each point, and the treatment duration. In addition to a review of the previous studies on low-level laser, the principles of Traditional Chinese Medicine were also studied.

In this LA study, a new energy dose (the irradiation energy for each acupuncture point was 5.4 J, the power density was 0.107 W/cm2, and the energy density was 19.26 J/cm2) and a different clinical protocol were employed. The results of the experiment indicated that the effect of LA on normal subjects was significant ($p < 0.05$). Both motor nerve conduction velocity and sensory nerve conduction velocity decreased significantly. The results suggested that the LA treatment could cause nerve conduction and the laser dosage used could cause significant biomedical stimulation. As a result, it was considered that the power density of 0.107 W/cm^2 used in the study was acceptable as an effective laser dosage for human subjects.

3.4.3 The Effects of Laser Acupuncture on Nerve Conduction Studies for Normal Subjects

Many researchers have shown an interest in the mechanism and clinical protocol of LLLT or LA. Some have focused on an exploration of the principle of analgesic effects by

LA through investigating the change of nerve functions. Rochkind et al. (1987) claimed that the low energy He-Ne laser could affect the electric activity and morphology in both intact and severely injured peripheral nerves of rats. Snyder-Mackler and Bork (1988) supported the contention that the application of low-level laser increased the distal latency of sensory nerves in normal subjects. They found that LLLT caused a significant increase in latency (μ = 0.37 msec, σ = 0.16 msec) on the peripheral sensory nerve. In 1993, Basford et al. (1993) found that percutaneous 830 nm continuous wave laser irradiation could affect median nerve function, but that the effects were quite limited and appeared to only occur on the distal portion of the nerve. Jarvis and his colleagues (1990) applied low-level laser to irradiate a rabbit's cornea to observe the effect of laser on Aδ- and C- fibre sensory afferents. They concluded that no alteration could be found.

In this experiment, according to correlation measures to analyse the intra-group differences between pre-treatment and post-treatment, and between pre-treatment and final baseline, the changes caused in the LA group were significant ($p < 0.001$), while most changes in the placebo group were insignificant ($p > 0.05$). This indicated that LA treatment could cause nerve conduction changes on all right upper extremities. It also indicated that LA caused a significant decrease in nerve conduction velocities. Not only does this support the results of the experiments done by Snyder-Mackler (1988) using low-level laser, but it also supports the idea that LA, which is a new method, could cause interference in nerve transmission. Thus, it is a possible mechanism for the analgesic effects.

Furthermore, there was a significant decreasing trend during the half hour following LA application. In measuring the MNCV test, the values of post-treatment, post-0, post-30, and the final baseline decreased significantly ($p < 0.001$). This did not indicate the different affects of LA over experimental time. In measuring anti-SNCV test for the difference between pre-treatment and post-0, p was 0.009. For ortho-SNCV it was 0.027. This indicated that the immediate effect of LA treatment was not very strong. When the effect after 30 minutes of LA application was compared with that after the whole stage of LA application, the results suggested that the effect caused by LA treatment was more significant over time.

CHAPTER 4
EXPERIMENT—THE EFFECTS OF LASER ACUPUNCTURE THERAPY IN PAIN TREATMENT ON PATIENTS WITH CARPAL TUNNEL SYNDROME

In this study, we investigate the effects of laser acupuncture (LA) therapy in pain treatment for patients suffering from carpal tunnel syndrome (CTS)— a common entrapment neuropathy. CTS causes pain in a person's hands. Previous research has suggested that LLLT can relieve pain in carpal tunnel syndrome sufferers (Weintraub, 1997; Padua et al., 1999; Wong et al., 1995) and LA therapy together with other treatments can cause analgesic effects (Branco et al., 1999). However, there are only a few publications involved in studying the effects of LA therapy as a unique treatment on relief pain. This chapter presents the research of using LA as mono-therapy for pain relief in CTS patients.

4.1 Objectives

There is a need to assess whether LA therapy is effective for reducing pain in an idiopathic CTS sufferer. The objectives of the research conducted were therefore to:

- Gather subjective feedback to assess whether any significant changes are caused by LA treatment.
- Obtain objective measurements of pain relief by measuring physical parameters.
- Examine whether there are any significant changes between different treatment stages based on regular evaluations.
- Examine whether there are any significant changes on NCV during the different treatment stages.

4.2 Methods

4.2.1 Selection of Subjects

Twelve patients, who were outpatients of the Queen Mary Hospital in Hong Kong, suffering from CTS were recruited. To be included in the study, a patient had to meet the following criteria:

- been suffering from bilateral CTS for six months or above with the condition confirmed by electro-physiological tests or typical clinical presentations and with pain as the subject's main symptom;
- aged between 20 to 70;
- had no previous history of injury to their hands or upper extremities, except CTS;
- had no previous history of LLLT or LA therapy;
- received no medication, massages, or other therapies in the previous month;
- be free of other diseases;
- was not pregnant.

4.2.2 Experimental Design

The experiment was carried out in two stages. During the first treatment stage, a randomised single-blind controlled experiment was established. One hand of each patient received a session of real LA treatment while the other hand received a session of sham LA treatment. Patients were unaware that only one hand was actually being treated. Subsequently, the second stage of treatment would ensue. In the second stage, bilateral hands of each patient received real LA treatment for one or two sessions, depending on the requirement. A session consisted of ten days of daily treatment and seven days of rest. If the symptoms of pain were not relieved following three sessions of treatments, LA treatment was discontinued and a different method was considered.

Before and after each session, patients were required to complete a McGill pain questionnaire and visual analogue scale. They also underwent physical examinations. In addition, NCSs were performed, the process for which was the same as with normal subjects (see Chapter 3).

4.2.3 Instruments

Of the apparatus used, only the dynamometer and pinch gauge will be described in detail here, as the laser therapy unit and the electro-diagnostic unit have already been covered in Chapter 3.

Dynamometer

A JAMAR™ Hand Dynamometer (Jackson MI 49203, U.S.) was used to test grip-strength (Figure 4.1). Dynamometer reliability was verified by determining the correlation between the grip-strengths of patients measured on separate occasions. A high correlation implies the instrument is reliable in producing repeated measurements. Ten healthy subjects, five male and five female, in the age range of 24 and 36 (μ = 29.2 years, σ = 3.74 years), were recruited from the Hong Kong Polytechnic University. Each subject was asked to sit with his or her shoulders adducted and neutrally rotated, elbow flexed at 90°, and forearm and wrist rested in neutral positions. With the dynamometer adjusted to the desired spacing (the second and third notch for females and males respectively) and the red peak-hold needle rotated counter-clockwise to zero, each subject was asked to squeeze with maximum strength, and the highest reading was recorded from the peak needle. Three measurements were taken for each hand in turn. After 30 minutes, the subject was asked to repeat the procedure. The correlation between the two sets of grip-strength measurements was r = 0.992 (Appendix III). The high correlation suggests that the instrument was reliable in its repeated measurements.

Pinch Gauge

A pinch gauge (BASELINE®, U.S.) was used for pinch-strength test (Figure 4.2). The reliability of the pinch gauge was verified in a manner similar to the dynamometer reliability test, and using the same healthy subjects. Each subject was asked to sit with his or her shoulders adducted and neutrally rotated, elbow flexed at 90° and forearm and wrist rested in neutral positions. Placing the gauge between the subject's thumb (top) and index finger (bottom) with the rest of the other fingers closing together, the subject was then asked to squeeze with their maximum strength. Three measurements were taken for each hand in turn. After 30 minutes the subject was asked to repeat the procedure. The correlation between the two sets of pinch-strength measurements was r = 0.985 (Appendix IV), suggesting the pinch gauge was reliable.

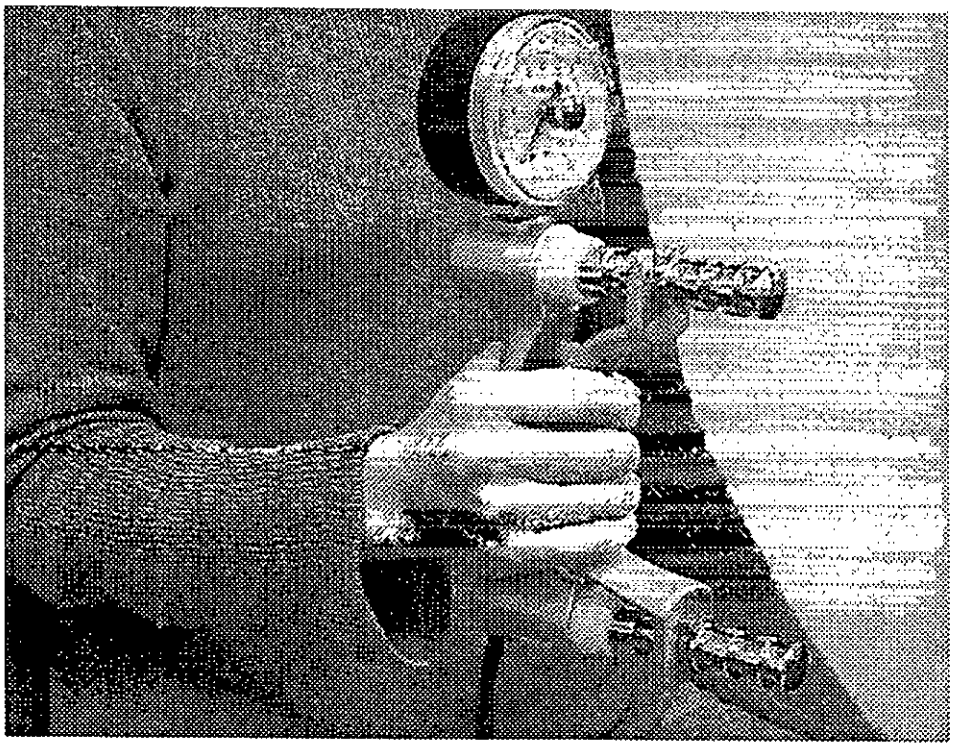

Figure 4.1. Grip strength measurement.

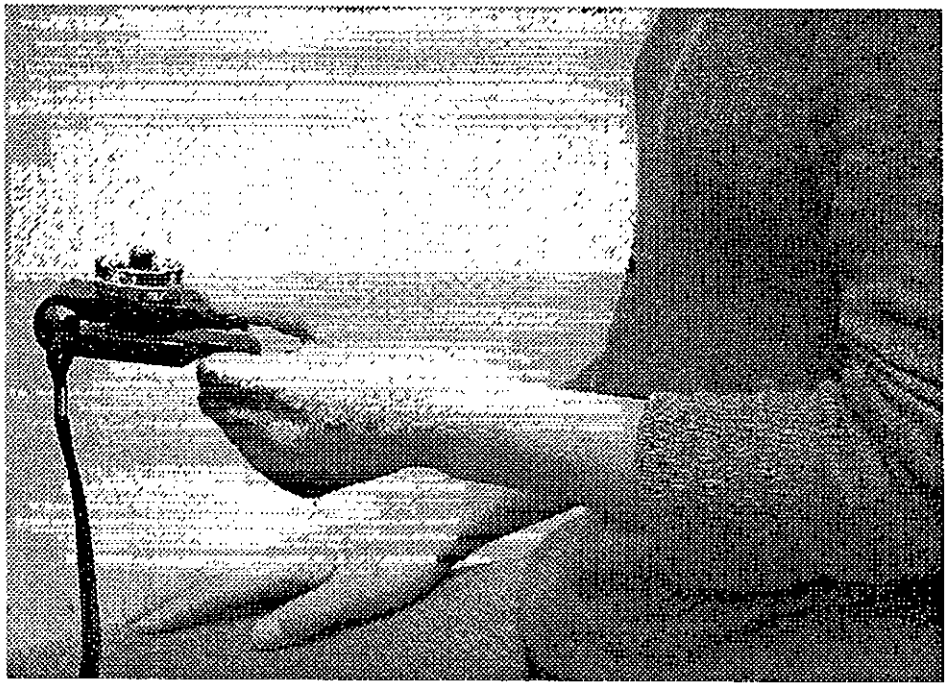

Figure 4.2. Pinch strength measurement.

4.2.4 Procedure

The basic preparations of environment and subject were the same as in the experiments on normal subjects. Except for a consent agreement, specific information pertaining to the patient was also collected. The information collected included weight, height, age, gender, professional information, health history, and a detailed description of the subject's pain condition.

LA was performed on four acupuncture points, namely, PC7, PC8, LI4, and TE4. The locations of these acupuncture points are described below. The criteria for selecting acupuncture points' locations were specified in Chapter 3.

LI 4 (Hegu) is on the dorsum of the hand, between the first and second metacarpal bones, in the middle of the second metacarpal bone on the radial side (Figure 4.3). This point is considered the most effective point for the relief of pain and helps to redress the balance of meridians around the hands.

TE4 (Yangchi) is on the transverse crease of the dorsum of the wrist, in the depression at the ulnar aspect of the tendon of muscle extensor digitorum communis (Figure 4.3). This point alleviates pain and numbness in the wrist.

PC 7 (Daling) is in the middle of the transverse crease of the wrist, between the tendons of muscle palmaris longus and muscle flexor carpi radialis (Figure 4.4). This point is associated with redressing the balance of meridians around the hands.

PC 8 (Laogong) is between the second and third metacarpal bones. When the fist is clenched, this point is just under the tip of the middle finger (Figure 4.4). Its function is the same as that of PC7.

The laser probe was placed directly on the subject's skin of the respective acupuncture point in perpendicular direction while the palm of the subject was placed horizontally facing up or down on the table. The laser irradiation lasted three minutes per point. Each subject received a total of 10 treatments during a continuous 10-day treatment session. Before and after the LA procedure every day, the subject was given a 20-minute break.

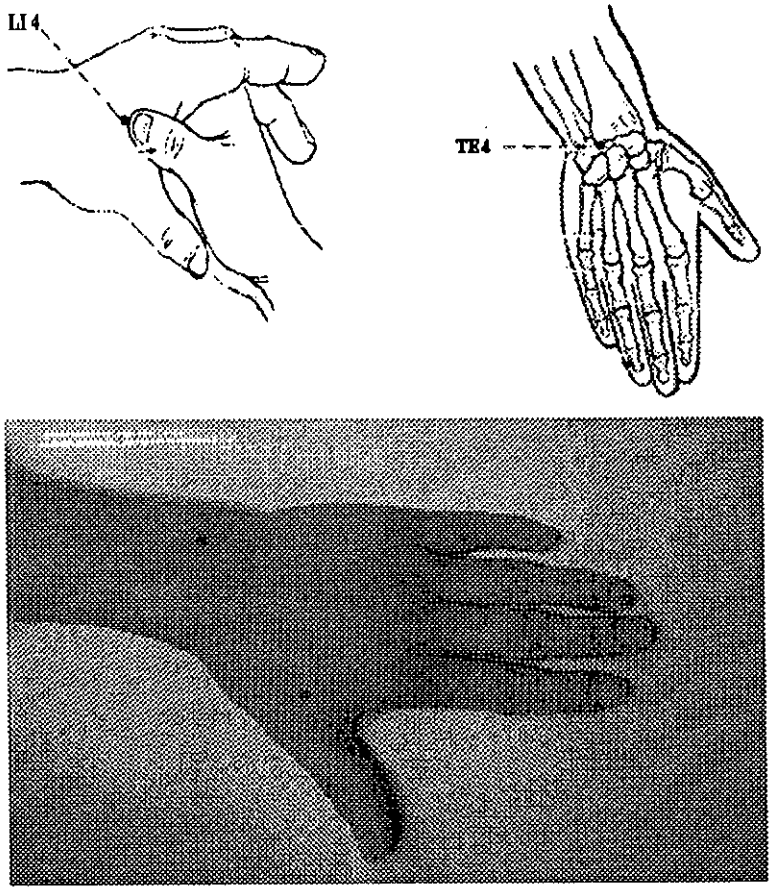

Figure 4.3. Locations of LI4 point and TE4 point.

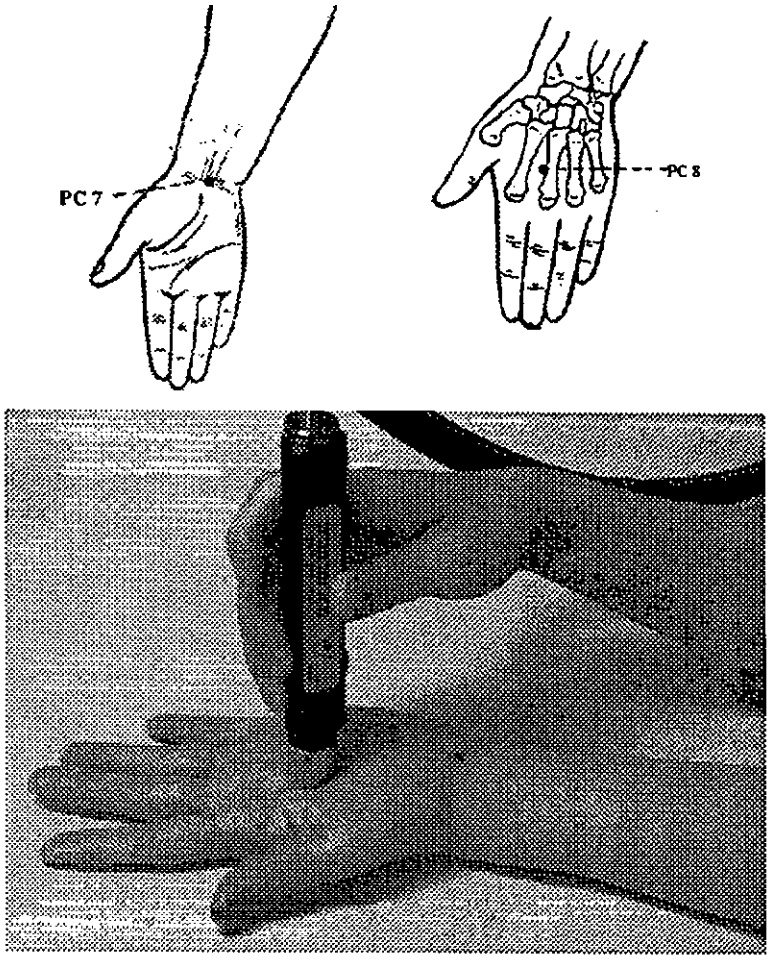

Figure 4.4. Locations of PC7 point and PC8 point.

4.2.5 Evaluations

Subjective feedback from the patient and objective measurements were collected throughout the treatment. Subjective feedback comprised the McGill pain questionnaire (MPQ) and the visual analogue scale (VAS). Objective measurements included a physical examination (Phalen's test), the monitoring of kinesiological properties (grip-strength test and pinch-strength test), and nerve conduction studies. A detailed description of these evaluation methods is presented below. Except for NCSs, all tests were conducted before and after every LA therapy session.

The McGill Pain Questionnaire

Devised by Melzack (1975), the McGill pain questionnaire is most commonly used for subjectively measuring the condition of pain. The McGill pain questionnaire is composed of 20 word groups, consisting of 78 adjectives. The subject can choose no more than one word in any group (or every group, if the subject wished) to describe his or her feeling about suffering pain. Each word is marked with a score. The questionnaire yields a number of different indices: the pain rating index (PRI), based on the scale values of words checked and which can be computed for the total questionnaire, ranges from 0 to 78; the present pain intensity (PPI), which is a rank score reflecting subject's pain intensity, is from 0 to 5; and the number of words chosen (NWC), which measures the number of words checked, ranges from 0 to 20. Higher scores indicate more severe symptoms.

In this study, a Chinese version of the McGill pain questionnaire was used. This Chinese version was strictly developed to eliminate cross-cultural semantic barriers that can occur from a purely literal translation (Nan et al., 1993). Before and after every session, each subject was asked to complete the questionnaire. PRI, PPI, and NWC scores were recorded and compared respectively. Calculating the difference between each pair of values for every treatment stage helped assess the effectiveness of the LA treatment.

The Visual Analogue Scale

The visual analogue scale (VAS) was considered to be one of the best methods available for estimating the intensity of pain. Since VAS is simple in its application, it is

used frequently (see Chapter 2). VAS is used to specify the extent of numbness and pain by a 10cm line rating from 0 (no pain or numbness) to 10 (maximally imaginable pain or numbness). Patients were asked to mark the point on the line corresponding to the pain experienced at the time of the test. The VAS test was performed before and after each session of LA. The difference in VAS values was used to provide an estimate of the effect of LA therapy.

Grip Strength Test

The grip strength test is one of the methods used to assess the extent of the kinesiological property of a subject's hand. A detailed procedure of this test was described in the above section on the dynamometer (see p. 73-74). Before and after every treatment session, the subject was asked to perform the test. Each time, the test was repeated three times and the mean value was recorded in kilograms. Higher values indicated that the kinesiological property of the hand was good. Comparing the changes in each session gave an indication of the effectiveness of LA therapy.

Pinch Test

The pinch test was another objective evaluation method used to test the kinesiological property of the subject's hand. The process was described in a previous section on pinch gauge (see p. 75-76). The mean of three successive measurements was recorded before and after each session. The value was recorded in kilograms also. A comparison of whether there was any change between before and after one session determined the effect of LA treatment on this subject.

Phalen's Test

Physical examination is a basic diagnostic tool, and a typical outcome measure in medical research (Gelberman et al., 1983; Golling et al., 1986; Feuersto et al., 1999; Homan et al., 1999). The physical examination for CTS traditionally includes sensibility evaluation via two-point discrimination, monofilament test, documentation of thenar muscle, strength and provocative test (Phalen's test and Tinel's test). Among these examinations, Phalen's

test has a sensitivity of 75% to 88% (Williams et al., 1992) and a specificity of 54% (Buch-Jaeger et al., 1994). Therefore, Phalen's test is probably the most reliable to diagnosis CTS as a physical examination (Tubiana et al., 1996). Besides, the operation of this test is very simple. This test is always done at first clinical visit. With both wrists in a fully flexed position for one minute, the appearance or exacerbation of paraesthesia in the median distribution is considered positive (see Figure 4.5). The closer the time is to zero second, the worse is the patient's condition. Phalen's test was performed once before and after every treatment session in this study. By comparing the changes at different times, the effectiveness of LA therapy could be evaluated.

Figure 4.5. Phalen's test.

Nerve Conduction Studies

As for NCSs, the measuring procedures of MNCV and SNCV were the same as for the normal subjects (see Chapter 3). Before the application of LA, NCV measurement was performed twice respectively on different days in order to define the baseline of NCV, which showed the original status of the median nerve. Then, 10 days of continuous LA treatment was started. During the session, on the first, fifth, and tenth day, the NCV was measured to

monitor the series median nerve conduction over this period. On these three days, the NCV was recorded in detail twice after LA treatments. The first occurred immediately after the end of the LA operation; the second after 30 minutes had elapsed from the end of the LA operation. This allowed the status of nerve conduction to be measured within a short time following LA treatment.

General Description—the GSS Grade

A baseline assessment of a patient's condition includes a standardised symptom questionnaire, rating five categories of symptoms (pain, numbness, paresthesia, weakness/clumsiness, and nocturnal awakening) on a scale from 0 (no symptoms) to 10 (severe). The total score in each of the five categories is termed the global symptom score (GSS) (Herskovitz et al., 1995; Chang et al., 1998). Higher scores indicate more severe symptoms. Based on the GSS, the patient is evaluated to determine which grade the hand is in, including grade 0 (GSS = 0); I (0 – 10); II (11 – 20); III (21 – 30); IV (31 – 40); and V (41 – 50). Before the start of the experiment and after every session, the evaluation of the GSS was performed for each affected hand to evaluate the effect of LA on the affected hand.

4.2.6 Follow-up

Two follow-up visits were carried out to observe the long-term therapeutic effect on each patient. The first follow-up was two months after the completion of the treatment. The second was six months after the completion of the treatment. Patients were asked to compare their current status with that experience prior to therapy and to provide feedback on their views on the success of the therapy.

4.3 Results

4.3.1 Statistical Analysis

Firstly, descriptive statistics were applied to describe the basic characteristics of the patient subjects. Secondly, for all outcome measurements, mean and standard deviation (SD) scores were calculated. All experimental values of every evaluation were analysed by

paired-samples t-test to measure the correlation to the intra-group changes. Also, one nonparametric method—the Wilcoxon signed-rank sum test—was used to confirm the results from *t* test. All of the mentioned statistical tests were performed using SPSS (10.0). A value of $P < 0.05$ was considered significant.

Only for Phalen's test, McNemar test was used for comparing the proportion of hands showing positive result. Because different subjects received one to three sessions of LA therapy, a generalised linear model for longitudinal data was used to observe the effects of LA on NCSs over time.

4.3.2 Subjects' Demographic Characteristics

Twelve patients with bilateral CTS were recruited and 24 hands were tested (12 hands in the placebo group and 12 hands in the LA group in the first stage). Patients' ages ranged from 39 to 67. The mean age was 50.33 years and the SD was 7.28. The age distribution of the patient subjects is shown in Table 4.1. Figure 4.6 shows that 8% of the patients were from 30 to 39, 50% were from 40 to 49, 34% were from 50 to 59, and 8% were from 60 to 69. All subjects were female. The occupation distribution is shown in Table 4.2. The results were categorised into six groups. Five of the patients were housewives, three were cleaners, one was a seamstress, one was a packer, one was a clerk, and one was a nurse. Figure 4.7 shows the analysis of occupational groups of the patient subjects.

Table 4.1. Frequency distribution of patient ages

Age range (year)	Frequency
30-39	1
40-49	6
50-59	4
60-69	1
Total	12

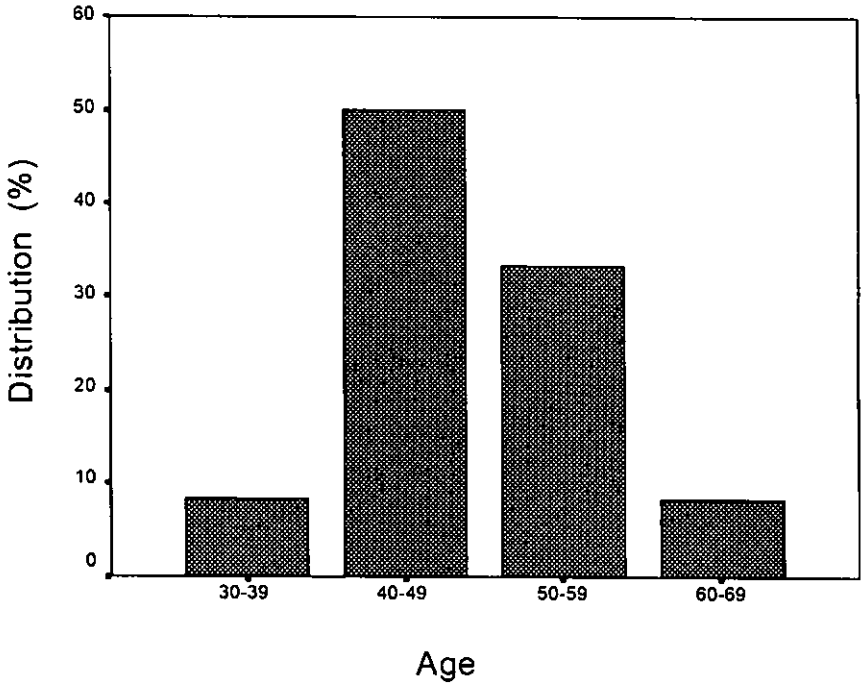

Figure 4.6. Distribution of age on patient subjects.

Table 4.2. Frequency distribution of patient occupations

Occupation	Frequency
Housewife	5
Clerk	1
Cleaner	3
Seamstress	1
Packing-worker	1
Nurse	1
Total	12

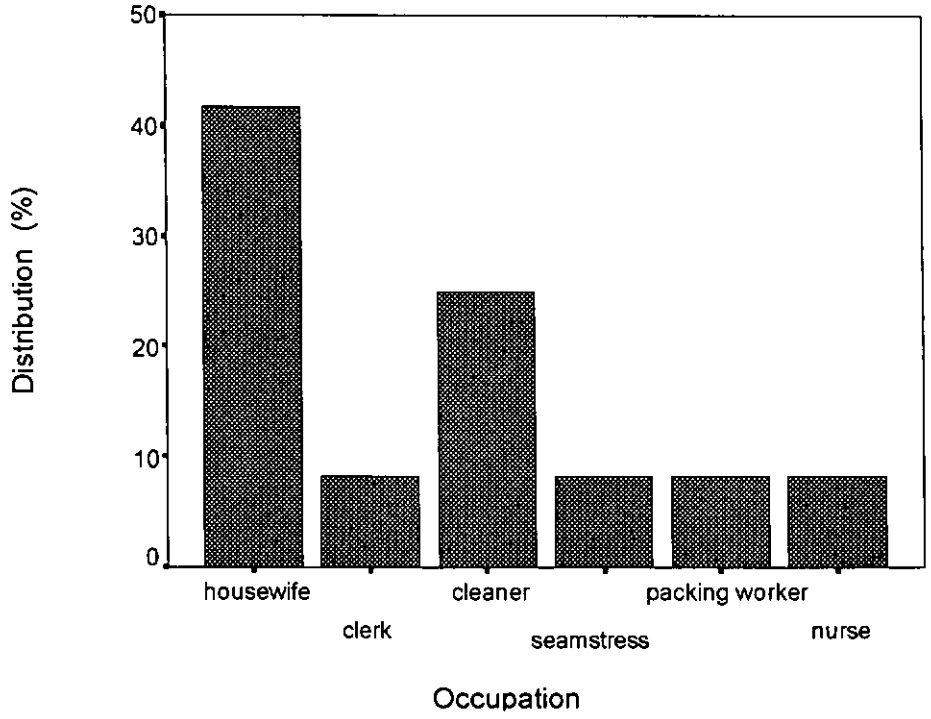

Figure 4.7. Distribution of occupation on patient subjects.

The severity of a patient's condition was categorised into six groups according to the GSS score, from 0 to V (shown in Table 4.3). The demographic data of the onset duration and previous therapies that patients received are shown in Table 4.4 and Table 4.5 respectively. The duration of symptom onset ranges from more than six months to more than 20 years. In the former table, in the placebo group, only one hand had less than one year for its onset duration, five hands' durations were between one to three years and half of the twelve hands had more than three years for their duration. In the LA group, six hands had durations of between one and three years, while the other six hands had more than three years as their duration. In the latter table, the results showed that before the LA therapy, many other physical therapies had been applied to the CTS patients. The patients were under conservative treatments of more than six months duration or decompression with unrelieved or worsening symptoms.

Table 4.3. Frequency distribution of the severity class of experimental hands in different groups according to GSS grade

Severity class	Frequency	
	Placebo group	LA group
0	0	0
I	0	0
II	2	1
III	8	8
IV	1	2
V	1	1
Total	12	12

Table 4.4. Frequency distribution of patient's CTS onset duration in different groups

CTS onset duration (year)	Frequency	
	Placebo group	LA group
< 1	1	0
1 to 3	5	6
> 3	6	6
Total	12	12

Table 4.5. Demographic data of symptom duration and previous treatment on hands in different group

Variable	Placebo group	LA group
Number of hands (n =)	12	12
Symptom Duration (year)	6.63 ± 8.14	6.54± 8.11
Previous treatment (n =)		
Medication	4	4
Prior splinting	5	5
Steroid injection	2	2
TENS	4	4
Acupuncture	1	1
Hydrotherapy	3	3
Kinesitherapy	2	2
Cold & heat therapy	1	1
Wax therapy	1	1
Ultrasound therapy	5	5
Surgical decompression	1	1

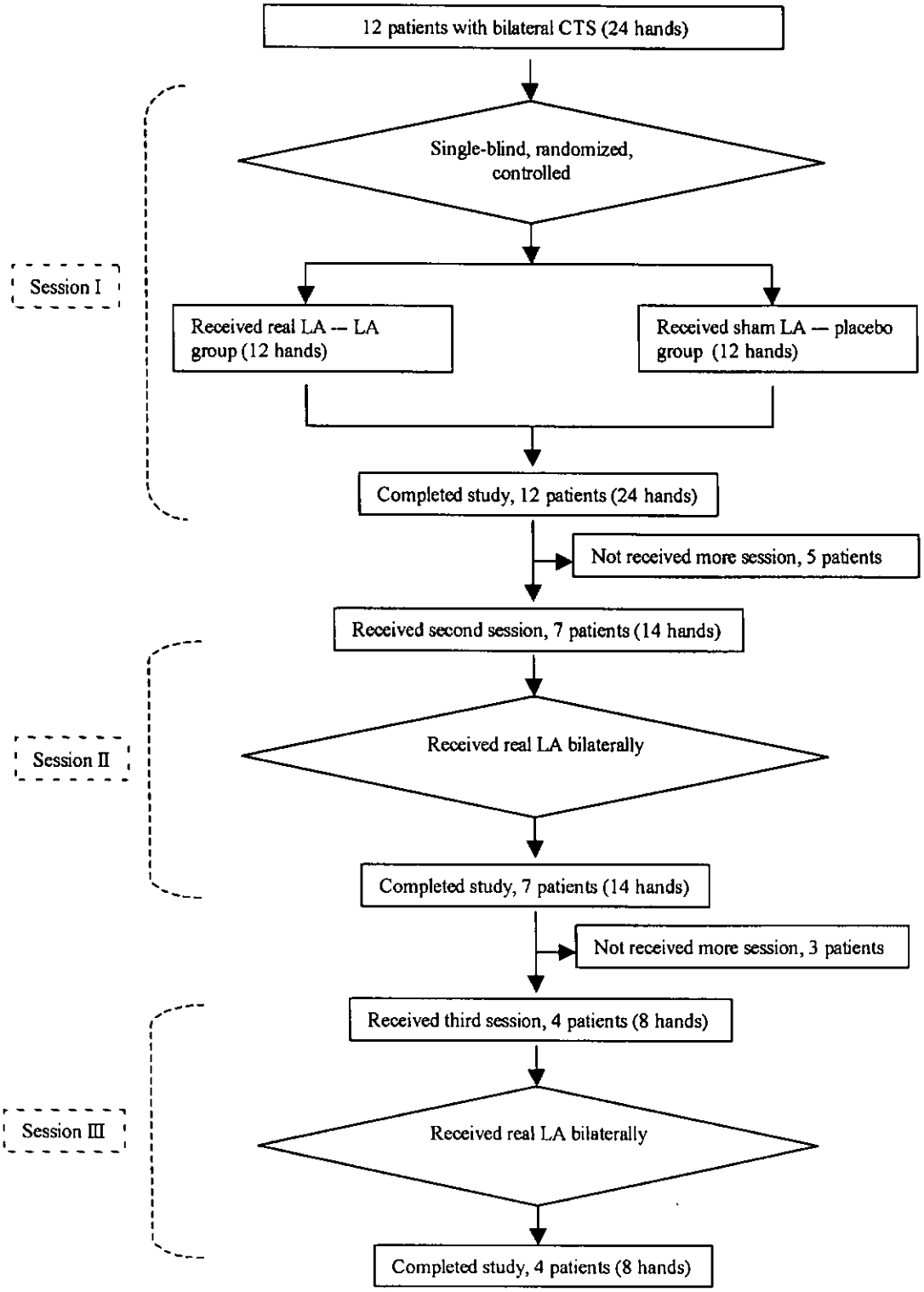

Figure 4.8. Flow-chart of the protocol of LA therapy on patients with CTS.

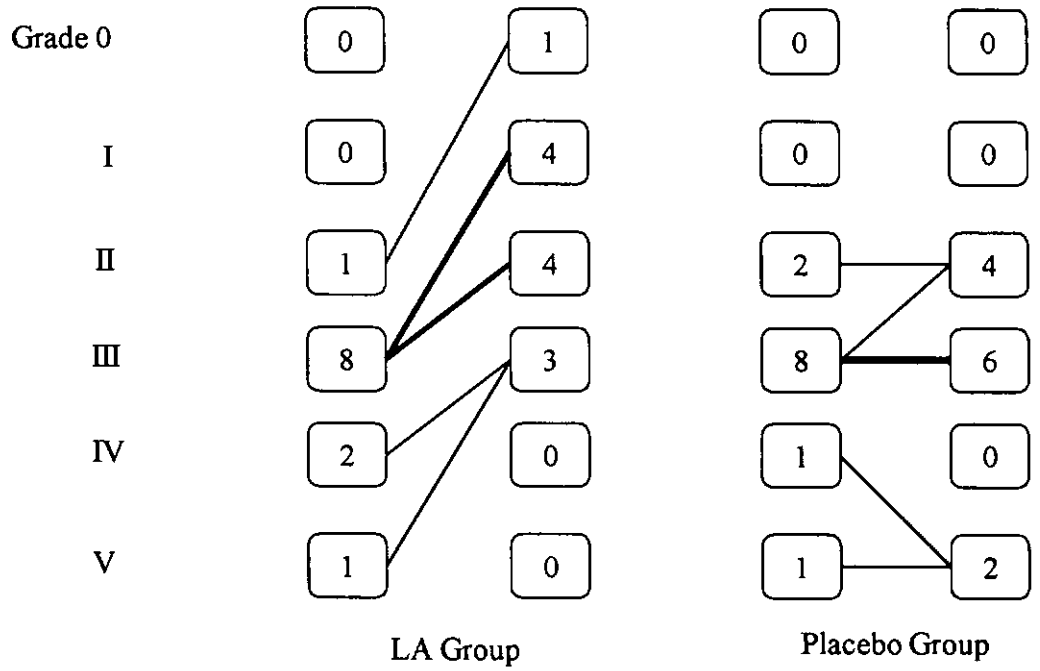

Figure 4.9. Quantification of amelioration of patient's status after the first session between LA group and placebo group according to the GSS Grade.

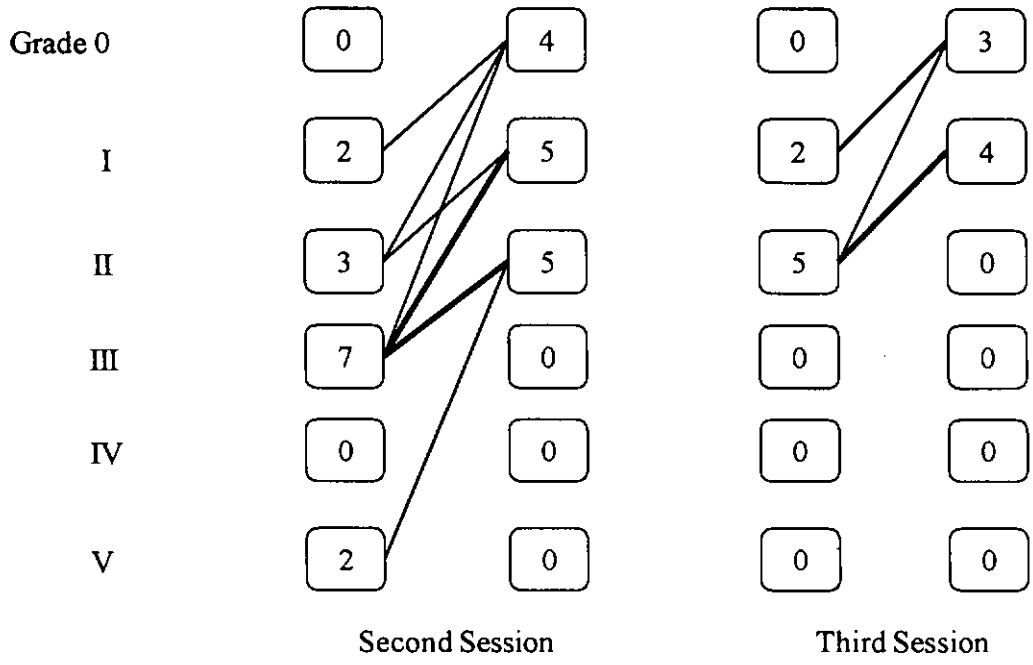

Figure 4.10. Quantification of amelioration of patient's status after the second and the third sessions according to the GSS Grade.

During the first stage, the experiment was designed as a randomised single-blind controlled study which twelve patients finished. Following the first stage, some of the 12 patients asked to undergo one more therapeutic session as their pain symptom still remained to some degree. No patient was given more than three treatments. There was a one-week interval between successive sessions. The reason for this interval was that each acupuncture point had to be rested in order to keep its sensibility. If a patient received one more treatment sessions, real LA was applied on both hands starting from the second stage.

Figure 4.8 shows a flow-chart of the protocol of LA therapy on patients with CTS and the condition of patients distributed in different sessions. The results showed that 12 hands in the LA group and 12 hands in the placebo group completed the first session of the study. In the second session there were seven patients because they wanted to receive one more LA treatment session for further improving their conditions. In the third session there were four (one of them just received LA treatment for one hand because she felt satisfied with the improved status of the other hand). Therefore, four hands received totally three sessions of LA treatment, 10 hands received two sessions, five hands received one session and five hands did not receive real LA treatment and withdrew from the experiment after finishing the first stage.

Figure 4.9 shows the GSS grade distribution of the affected hands of the patients before and after the first session in different groups. The results show the quantification of the amelioration of a patient's status after the first stage between the LA group and the placebo group according to the GSS Grade. Figure 4.10 shows that quantification of the amelioration of a patient's status after the second and third LA treatments according to the GSS Grade.

4.3.3 Experimental Findings in Stage I

Experimental Findings of Subjective Evaluations

Subjective evaluations included the McGill pain questionnaire and the VAS. Four indices were measured, namely, the NWC, PRI, PPI, and VAS values. Table 4.6 and Table 4.7 show the experimental results of these subjective indices in Stage I. The first table

shows the results of paired-samples t-test and the second of Wilcoxon signed-ranks test. In the tables, the measured correlation to the intra-group change during the first stage was shown. The results indicated that in the placebo group there was insignificant improvement ($p > 0.05$) while in the LA group there was improvement in each evaluation ($p < 0.05$). In addition, it achieved in the LA group a reduction of 47.5% in VAS, of 44.3% in NWC, of 57.2% in PRI and of 53.2% in PPI after a session of LA. The result means that LA can improve the condition of patients with CTS after only one LA therapy session. Because the study was designed as a randomised single-blind controlled experiment during the first stage, the patients did not know that each of their hands received a different kind of treatment. Therefore, the experimental results indicate that there was no placebo effect on the controlled hand.

Experimental Findings of Physical Examinations

Using the same statistical procedures as with subjective examinations, the results of the grip strength test and the pinch strength test are shown in Table 4.8 (using paired-samples t-test) and Table 4.9 (using Wilcoxon signed-ranks test). The result of the grip strength test was similar to the subjective evaluations. The test showed that in the placebo group there was no significant difference before and after the first stage ($p = 1.000$). However, in the LA group, the result of the test indicated that there was significant change caused by LA therapy ($p = 0.042 < 0.05$). The result indicated that LA therapy improved the condition of the patients. Similar result did not been found in pinch strength test.

Besides, the Phalen's test was analysed by McNemar test for comparing its rate of positive proportion (Sheskin, 1996). In baseline evaluation in Stage I, 10 of 12 hands (83.3%) showed Phalen's test to be positive in both treatment and placebo groups. Phalen's test became negative in 2 hands (20%) in the LA group, compared with no variation in the placebo group.

Findings in Nerve Conduction Studies

As for the nerve conduction studies, values including MNCV, anti-SNCV, and ortho-SNCV were collected using the same process as used in the experiment on normal subjects.

Table 4.6. Outcome of correlated measures using paired-samples t-test on subjective evaluations in Stage I

Paired-samples t-test	Placebo group			Real LA group		
	Baseline (pre-test)	After 1st session	*p* (n = 12)	Baseline (pre-test)	After 1st session	*p* (n = 12)
VAS	3.33 ± 1.53	3.00 ± 1.33	0.232	5.71 ± 2.13	3.00 ± 1.93	<0.001
NWC	7.75 ± 3.44	7.67 ± 3.47	0.857	10.33 ± 2.53	5.75 ± 4.05	<0.001
PRI	11.50 ± 5.70	13.08 ± 8.24	0.376	23.00 ± 12.73	9.83 ± 10.09	0.018
PPI	1.33 ± 0.65	1.25 ± 0.62	0.339	2.50 ± 1.24	1.17 ± 0.72	<0.001

Table 4.7. Summary of statistical results of subjective feedback on patient subjects by Wilcoxon signed-ranks test in Stage I

Wilcoxon signed-ranks test	Placebo group			Real LA group		
	Baseline (pre-test)	After 1st session	*p* (n = 12)	Baseline (pre-test)	After 1st session	*p* (n = 12)
VAS	3.33 ± 1.53	3.00 ± 1.33	0.196	5.71 ± 2.13	3.00 ± 1.93	0.002
NWC	7.75 ± 3.44	7.67 ± 3.47	0.834	10.33 ± 2.53	5.75 ± 4.05	0.002
PRI	11.50 ± 5.70	13.08 ± 8.24	0.513	23.00 ± 12.73	9.83 ± 10.09	0.002
PPI	1.33 ± 0.65	1.25 ± 0.62	0.317	2.50 ± 1.24	1.17 ± 0.72	0.004

Table 4.8. Summary of statistical results of physical examinations on patient subjects by paired-samples t-test in Stage I

Paired-samples t-test	Placebo group			Real LA group		
	Baseline (pre-test)	After 1st session	*p* (n = 12)	Baseline (pre-test)	After 1st session	*p* (n = 12)
Grip strength (kg)	18.84 ± 4.15	18.84 ± 5.06	1.000	17.84 ± 5.78	19.10 ± 6.46	0.042
Pinch strength (kg)	5.63 ± 1.73	5.91 ± 1.73	0.016	5.38 ± 1.78	5.63 ± 1.69	0.095

Table 4.9. Summary of statistical results of physical examinations on patient subjects by Wilcoxon signed-ranks test in Stage I

Wilcoxon signed-ranks test	Placebo group			Real LA group		
	Baseline (pre-test)	After 1st session	*p* (n = 12)	Baseline (pre-test)	After 1st session	*p* (n = 12)
Grip strength (kg)	18.84 ± 4.15	18.84 ± 5.06	0.814	17.84 ± 5.78	19.10 ± 6.46	0.056
Pinch strength (kg)	5.63 ± 1.73	5.91 ± 1.73	0.033	5.38 ± 1.78	5.63 ± 1.69	0.113

Table 4.10. Summary of statistical results of nerve conduction tests on patient subjects by paired-samples t-test in Stage I

Paired-samples t-test	Placebo group			Real LA group		
	Baseline (pre-test)	After 1st session	*p*	Baseline (pre-test)	After 1st session	*p*
MNCV (m/s)	52.94 ± 6.22	52.92 ± 7.10	0.958 (n = 12)	46.62 ± 10.59	50.67 ± 9.94	0.080 (n = 12)
Anti-SNCV (m/s)	42.71 ± 20.87	43.58 ± 16.38	0.710 (n = 10)	35.18 ± 22.44	35.92 ± 19.42	0.779 (n = 9)
Ortho-SNCV (m/s)	43.60 ± 15.83	42.92 ± 15.53	0.235 (n = 10)	30.91 ± 22.61	31.92 ± 20.85	0.666 (n = 8)

Table 4.11. Summary of statistical results of nerve conduction tests on patient subjects by Wilcoxon signed-ranks test in Stage I

Wilcoxon signed-ranks test	**Placebo group**			**Real LA group**		
	Baseline (pre-test)	After 1st session	*p*	Baseline (pre-test)	After 1st session	*p*
MNCV (m/s)	52.94 ± 6.22	52.92 ± 7.10	0.638 (n = 12)	46.62 ± 10.59	50.67 ± 9.94	0.023 (n = 12)
Anti-SNCV (m/s)	42.71 ± 20.87	43.58 ± 16.38	0.325 (n = 10)	35.18 ± 22.44	35.92 ± 19.42	0.539 (n = 9)
Ortho-SNCV (m/s)	43.60 ± 15.83	42.92 ± 15.53	0.075 (n = 10)	30.91 ± 22.61	31.92 ± 20.85	0.953 (n = 8)

Among the hands tested in the experiment, some hands had normal nerve conduction velocities before the start of the experiment (2 in LA group and 2 in placebo group), that were suffering from typical clinical presentations. Clinical diagnosis was very evident to these patients according to the characteristic symptoms of CTS, though their nerve conduction velocities had not decreased. Feldman (1987) offered criteria to define the different stages of CTS and he pointed that the patients with early CTS had nocturnal or at rest paresthesia and produced no findings on specialized tests. Therefore, these patients were still included in this experiment. Besides, the data of SNCV could not be collected for some hands due to the severity of their abnormal conditions. Therefore, during the data analysing procedure, missed data were excluded.

During the statistical procedure, as for these three sorts experimental data, there were several averages compared according to some relationships. These averages included the pre-treatment velocity presented, the average of nerve conduction measurements over two times before the beginning of the laser therapy (once, the day before the first day of LA applications, and the second time was on the first day immediately before laser therapy), the average of all nerve conduction velocity values taken after the beginning of LA application (marked as post-treatment), the average of all values taken immediately on the first, the fifth, and the tenth day (marked as post-0), the average of all values taken after 30 minutes of every time LA application on the first, the fifth, and the tenth day (marked as post-30). In Table 4.10 (using paired-samples t-test) and Table 4.11 (using Wilcoxon signed-ranks test), the results show the statistical significances of NCSs. During the first stage, only MNCV was to show an improvement in the LA group (using Wilcoxon signed-ranks test, $p < 0.05$).

Similar results were not found for SNCV. To further explore NCSs, the statistical procedure with normal subjects was performed as well. Table 4.12 shows the descriptive statistics of electro-diagnostic findings on patient subjects during the first stage, including the means and standard deviations over different measuring times for pre-treatment, post-treatment, post-30, and post-0. The three different tests of electro-diagnosis were conducted by two-samples t-test and Wilcoxon signed-rank sum test. The statistical results of these tests are listed in Table 4.13 and Table 4.14. For MNCV, the results from both of these tables indicate that in the LA group there were significant changes ($p < 0.05$) and in the

Table 4.12. Descriptive statistics of the nerve conduction velocity on patient subjects during the first stage

Nerve conduction velocity (m/s)		Placebo group	LA group
MNCV (n = 12)	Pre-treatment	53.30 ± 6.46	46.62 ± 10.59
	Post-treatment	53.07 ± 6.55	50.89 ± 9.00
	Post-0	53.15 ± 6.56	50.44 ± 9.34
	Post-30	52.98 ± 6.55	51.33 ± 8.67
Anti-SNCV (n = 10; 9)	Pre-treatment	48.31 ± 9.09	46.39 ± 9.03
	Post-treatment	47.87 ± 9.26	47.09 ± 9.49
	Post-0	48.11 ± 9.45	47.58 ± 9.17
	Post-30	47.64 ± 9.10	46.60 ± 9.86
Ortho-SNCV (n = 9; 8)	Pre-treatment	47.44 ± 9.74	45.29 ± 9.75
	Post-treatment	47.10 ± 9.31	46.00 ± 10.16
	Post-0	47.21 ± 9.55	46.54 ± 9.82
	Post-30	46.98 ± 9.09	45.45 ± 10.54

Table 4.13. Summary of statistical results of NCSs on patient subjects by paired-samples *t*-test during the first stage

Paired-samples *t*-test		Placebo group	LA group
		p	*p*
MNCV (n = 12)	Pre-treatment and post-treatment	0.293	0.010
	Pre-treatment and post-0	0.473	0.014
	Pre-treatment and post-30	0.225	0.008
	Post-0 and post-30	0.284	0.018
Anti-SNCV (n = 10; 9)	Pre-treatment and post-treatment	0.140	0.279
	Pre-treatment and post-0	0.546	0.030
	Pre-treatment and post-30	0.054	0.807
	Post-0 and post-30	0.131	0.116
Ortho-SNCV (n = 9; 8)	Pre-treatment and post-treatment	0.337	0.271
	Pre-treatment and post-0	0.489	0.101
	Pre-treatment and post-30	0.306	0.806
	Post-0 and post-30	0.478	0.086

Table 4.14. Summary of statistical results of NCSs on patient subjects by Wilcoxon signed-ranks test during the first stage

Wilcoxon signed-ranks test		Placebo group	LA group
		p	*p*
MNCV (n = 12)	Pre-treatment and post-treatment	0.367	0.015
	Pre-treatment and post-0	0.530	0.023
	Pre-treatment and post-30	0.272	0.010
	Post-0 and post-30	0.480	0.019
Anti-SNCV (n = 10; 9)	Pre-treatment and post-treatment	0.091	0.161
	Pre-treatment and post-0	0.533	0.036
	Pre-treatment and post-30	0.041	0.263
	Post-0 and post-30	0.248	0.093
Ortho-SNCV (n = 10; 8)	Pre-treatment and post-treatment	0.075	0.161
	Pre-treatment and post-0	0.213	0.093
	Pre-treatment and post-30	0.062	0.674
	Post-0 and post-30	0.594	0.050

placebo group correspondingly significant changes were not found. For SNCV, only in the anti-SNCV test there was a significant change in the LA group between pre-treatment and post-0.

4.3.4 Other Experimental Findings

The results shown above revealed that the effect caused by real LA was significant during the first stage. What were the differences if the affected hands received more than one session of LA treatment? There were nineteen out of twenty-four hands to receive more than one session treatment in this study. Table 4.15 and Table 4.16 show the results of the correlation between the outcome values before the first LA application and following the final LA application on the treated hands. Table 4.15 shows the results of paired-samples t-test and Table 4.16 shows the results of Wilcoxon signed-ranks test.

On subjective feedback, the improvement was very significant ($p < 0.001$), as indicated by the pre-test and final values measured after patients had received all the LA treatment. At the end of the whole experiment, it achieved in average a reduction of 76.1% in VAS, of 73.7% in NWC, of 81.2% in PRI and of 73.3% in PPI. Theses score were reduced to zero in eight hands of six patients. Compared with the results during the first stage, the improvement was more significant if the patient received one more LA session.

According to the findings of physical examinations, the final evaluation also indicated that LA therapy could improve a patient's affected hand significantly. Although no significant change was found in the LA group during the first stage, the final evaluation of the pinch strength test showed that LA therapy had a positive effect on patients. Besides, for the final evaluation, Phalen's test became negative in 10 hands and it demonstrated significant improvement in patients' conditions by LA treatment ($p < 0.001$). Therefore, it indicated that the improvement was more significant if the patient received one more LA session. Significant changes also were shows by the results of NCSs. The final evaluation of motor nerve conduction indicated that the effect of LA treatment was significant ($p = 0.010$ using paired-samples t-test; $p = 0.005$ using Wilcoxon signed-ranks test).

Table 4. 15. Outcome values of final evaluation using paired-samples *t*-test

Paired-samples *t*-test	Baseline value	Final follow-up value	*P* (n=19)
VAS	4.55 ± 2.40	1.18 ± 1.43	<0.001
NWC	9.00 ± 3.43	2.47 ± 3.13	<0.001
PRI	18.16 ± 12.46	3.26 ± 4.19	<0.001
PPI	2.00 ± 1.20	0.53 ± 0.51	<0.001
Rate of positive Phalen's test	16/19 (84.21%)	9/19 (47.37%)	<0.001
Grip strength (kg)	18.24 ± 5.39	20.79 ± 5.92	<0.001
Pinch strength (kg)	5.44 ± 1.78	6.15 ± 1.87	<0.001
MNCV (m/s)	48.30 ± 9.22	51.84 ± 7.73	0.010
Anti-SNCV (m/s)	47.91 ± 7.64	48.67 ± 8.47	0.131 (n = 15)
Ortho-SNCV (m/s)	46.03 ± 8.12	48.14 ± 9.64	0.139 (n = 14)

Table 4.16. Outcome values of final evaluation by Wilcoxon signed-ranks test

Wilcoxon signed-ranks test	Baseline value	Final follow-up value	*P* (n=19)
VAS	4.55 ± 2.40	1.18 ± 1.43	<0.001
NWC	9.00 ± 3.43	2.47 ± 3.13	<0.001
PRI	18.16 ± 12.46	3.26 ± 4.19	<0.001
PPI	2.00 ± 1.20	0.53 ± 0.51	<0.001
Rate of positive Phalen's test	16/19 (84.21%)	9/19 (47.37%)	<0.001
Grip strength (kg)	18.24 ± 5.39	20.79 ± 5.92	0.001
Pinch strength (kg)	5.44 ± 1.78	6.15 ± 1.87	<0.001
MNCV (m/s)	48.30 ± 9.22	51.84 ± 7.73	0.005
Anti-SNCV (m/s)	47.91 ± 7.64	48.67 ± 8.47	0.149 (n = 15)
Ortho-SNCV (m/s)	46.03 ± 8.12	48.14 ± 9.64	0.031 (n = 14)

Besides, in NCSs, the three groups of data collected from the three therapeutic sessions including MNCV, anti-SNCV, and ortho-SNCV were analysed by a general linear model for longitudinal data, a model that specialises in distinguishing data changes over time within individuals (Altman, 1991; Diggle et al., 1996). The model is shown below:

$$Y_{ij} = \alpha_i + \beta_k t_{ij} + \varepsilon_{ij},$$

where i is the individual, j is the different time, α_{ij} is the random effect of the individual, and ε_{ij} is a mean-zero deviation. The results are listed in Table 4.15.

Table 4.17. Fixed effect estimates of nerve conduction velocities during three treatment sessions

	Session one	Session two	Session three
Estimates of motor nerve conduction	0.0594 (n = 19)	0.0585 (n = 10)	0.0169 (n = 4)
Estimates of anti-sensory nerve conduction	-0.2899 (n =15)	0.1766 (n = 7)	0.2059 (n = 3)
Estimates of ortho-sensory nerve conduction	-0.0098 (n = 14)	0.0642 (n = 7)	0.2827 (n = 2)

4.3.5 Follow-up

The first follow-up was made two months after the completion of the treatment. The results show that the hands of the patients that received LA remained in an improved condition. The outcome was rated as "fair" by one patient (8.3%), as "good" by 8 patients (66.7%) and as "excellent" by 3 patients (25.0%). The second follow-up was six months after the completion of the first treatment course. In that follow-up, 25% of the patients complained that their symptoms had returned to a small extent.

4.4 Discussion

4.4.1 Discussion on the Experimental Design

During the processes of experiment and research on attenuating pain, the problem arises concerning whether it is necessary to set up a control group. Pain is regarded as an unpleasant sensory-based perception. There are many elements that can affect the sensation of pain. But why is this so? Although the symptom of pain is mostly caused by real pathogenic factors of the relevant tissues or organs, other elements—apart from medicinal therapies—such as resting, being in a happy mood, and so forth, can reduce the degree of the pain to some extent. One of the more important factors in attenuating pain is, in fact, psychological. For the results of new research to be considered reliable, it should not be easily accepted without any controlled group. From a strictly scientific viewpoint, it is therefore necessary to set up a controlled group when new forms of therapy are tested.

To reduce the degree of the effect of psychological factor, controlled double-blind studies can be used. More and more researchers work under double-blind tests and it is generally regarded as the "gold standard" (Naeser, 1997). The double-blind test means that neither the patient nor the therapist who is in charge of the diagnosis and evaluation of the study knows which group a patient is in. Only the operator who uses the therapeutic equipment knows the details so as to ensure a patient gets the relevant therapy or the placebo. In some studies, each subject is identified by a code number, and their true identity is only revealed at the end of the study (Laakso et al., 1997). The laser light of LLLT or LA is emitted under conditions of no heat, sound, or vibration. Thus, it is possible to construct a placebo laser apparatus indistinguishable from the active laser.

But more researchers are needed to participate in a double-blind study. For this reason, a single-blind test was used in this study, in which each of a patient's hands was randomly arranged to be either in the treated group or the controlled group, without the patient's knowledge. The operator of the equipment was responsible for controlling all the experimental factors during the whole experiment and ensuring that patients were not affected by psychological factors.

A debatable point emerged from the design of the study. Was there any interaction between a patient's two hands? Because one hand of a patient was treated by real LA while the other was treated by sham LA during the first session. If there was an interaction between a patient's two hands, it would be very difficult to measure the effect of LA therapy. As a hypothesis, it was regarded that there was no such interaction between hands of subject. The results from Chapter 3 showed that on normal subject in controlled group, there was no significant change before and after treatment, while there was a very significant change in LA group. It supported the hypothesis for the experiment on patients. It suggested that the effect of LA was local effect, not general body effect.

There was another question on the experimental design. It was the choice of acupuncture points for the patients with CTS. Totally, four acupuncture points including LI4, TE4, PC7 and PC8 were chosen according to the relevant theory of TCM (Chen et al., 1996; Long et al., 1999).

4.4.2 Discussion on Experimental Results

Acupuncture is an important component of TCM. Following the development of modern scientific methods, some alternatives to metal needles have appeared, such as microwave, ultrasonic, and magnetic acupuncture (Wong et al., 1992). Since the early 1970s, to reduce pain, low-level lasers have been used to stimulate acupuncture points instead of metal needles. Besides this main application, LA is also applied for prostatitis, female infertility, the healing of wounds, and even in veterinary practice. Hitherto, though many studies have used LA as an analgesic method, the basic theory has not been established completely that LA has not become a mono-therapy applied in present-day clinical medicine.

Previous research has suggested that LLLT can relieve pain in CTS sufferers. In most studies, laser light often irradiates on trigger points or key points. Wong and his colleagues (1995) treated 35 hands with LLLT on trigger points. Following up these cases, the results showed that 33 cases had pain relief and 2 cases had reduced pain. Weintraub (1997) reversed CTS in 77% of cases using LLLT on 5 points along median nerve course. Padua et al (1999) used one pulsed wave laser light on key points of 17 hands and reached transitory improvements. Besides, Branco and Naeser (1999) used LA together with other

treatments on 36 patients. As results, 33 of 36 hands (91.6%) were improved. Follow-up after 1-2 years with cases less than 60, only in 2 out of 23 hands (8.3%), pain returned, but was successfully re-treated within a few weeks.

What are the results of pain relief by laser therapy, which is as a mono-therapy for the patients with CTS? In this study, LA wa applied as a mono-therapy for treating pain caused by CTS under an effective protocol. Within chosen therapeutic parameters, LA therapy could bring about improvement in CTS patients. Subjective evaluations including the McGill pain questionnaire (three indices, NWC, PRI, and PPI) and the VAS showed significant improvement ($p < 0.001$). After LA treatment, there were improvements of 73.7% in NWC, of 81.2% in PRI, of 73.3% in PPI and of 76.1% in VAS. Among the objective evaluations, Phalen's test and one of the kinesiological assessments—the grip strength test—indicated that a patient's condition had improved ($p < 0.05$). As for the other kinesiological assessment—the pinch test—LA therapy was not found to have led to significant changes after only one session of LA treatment. However, based on the final evaluation of this test, it was found that LA therapy caused significant effects to the hand after more sessions. The results of grip test and pinch test indicated that the strength increased significantly after the LA treatment. After final evaluation, Phalen's test became negative in 10 hands (53%). Besides the above supplementary methods used to evaluate the effects of LA on pain relief, NCSs were also used in the study. Motor nerve conduction velocities, which were measured both immediately and 30 minutes after LA application, increased ($p < 0.05$), while it was not found that sensory nerve conduction velocity increased significantly during the first stage. Further, a general linear mode for longitudinal data was used to assess the increasing trend of variables over the sessions of treatment. The results showed the increasing trend of motor nerve conduction velocity decreasing over time and the trend of sensory nerve conduction velocity increasing even more over time. Sensory nerve conduction velocity varied a great deal in the early course compared to the motor nerve conduction change in a carpal tunnel syndrome patient (Schroeder et al., 1996). In this study, the results showed that the effect of LA was not the same as the sensory nerve conduction and the motor nerve conduction. In general, LA therapy caused a significant improvement in patients after just one session. All evaluations indicated that two or more

sessions of LA treatment caused patient's conditions to improve more significantly. The improved condition could keep after two months. After six months, 25% of the patients complained that their symptoms had returned to a small extent.

In this study, totally twelve patients (twenty-four hands) were recruited and these subjects had to follow serious criteria. Besides, a randomised single-blind controlled experiment and a longer-term investigation were carried out. The factor of sample error had been considered in this study. Therefore, the results were reliable though the sample was not big.

Results of this study demonstrated that the LA treatment resulted in improvement of symptoms of the treating hand without affecting the symptoms of the contralateral placebo hand. This observation indicated that the effect of LA is local rather than general. It was not difficult to explain why the CTS could be cured by application of LA on the selected acupuncture points (LI4, TE4, PC7 and PC8) distant from the injured site, if it was to compare the explanation of pathogenesis of CTS in western medical science and that in traditional Chinese medicine. In the western medical science, CTS is a common entrapment neuropathy with pain, reduced median nerve conduction velocity, and so forth. The carpal tunnel is a semi-rigid conduit that contains the median nerve and the nine digital flexor tendons with little free space. Any process either increasing the volume or reducing its capacity results in compression of the median nerve. During the pathological process, the increased pressure leads to mechanical distortion or ischemia of the median nerve. Following this, alterations of fluid balance and peripheral tissue edema may occur (Baxter-Petralia, 1990). Obstruction of the venous return in the epineural and perineural vascular plexuses causes anoxia and endoneural edema of the nerve (Evermann, 1988; Mackinnon et al., 1988). Accompanying the inflammatory response and edema formation, chemical mediators are released that cause pain, such as histamine, kinnis, proteolytic enzymes, and other substances (Guyton, 1991).

To treat this disease, two clinical studies, without control groups, using traditional acupuncture were conducted. Chan (1990) and Wolfe (1995) observed respective success rates of 97.2% for 35 of 36 and 87.5% for 14 of 16 carpal tunnel syndrome cases. Traditional acupuncture is a main therapeutic branch of traditional Chinese medicine, dating

back to around 2000BC. It is based upon the stimulation of well-defined points on the body by the insertion of metal needles. Such needling is considered necessary to redress the balance of yin and yang and the flow of Qi, and energy, which according to traditional Chinese medicine theory is considered to be disrupted when the body suffers from disease. Acupuncture therapy predates modern medicine by many years and now has found increasing acceptance worldwide—at least as an effective analgesic therapy. Therefore, more researchers are focusing on exploring the essentials of traditional acupuncture by the use of modern medical methods. Andersson and Lundeberg (1995) claimed that acupuncture caused the release of endogenous opioids and oxytocin, which inhibited pain. Alavi et al. (1996, 1997a, 1997b) stated that another mechanism of acupuncture on pain relief was increased blood flow. They observed a change of approximately +25% in blood flow post-acupuncture in the thalamus of four of five patients suffering from pain. The result was verified by Naeser (1997a). All this evidence suggests that it is possible to treat carpal tunnel syndrome by traditional acupuncture.

The cause of CTS in traditional Chinese medicine is due to stagnation of Qi and blood stasis (Cheng et al., 1993). Qi is the commander of blood. As long as Qi is made to move smoothly in the meridian, the unbalanced function of the blood would turn to normal, therefore, the stagnation of blood will disappear naturally. Until now, though there is not enough evidence to prove the existence of Qi and meridian, it could be considered that Qi and meridian were related to micro-circulation. Once there is a blockage or delay of micro-circulation, the pathological process of CTS might occur. The region of all acupuncture points selected are rich in blood vessel networks: there are the palmar arterial and venous network of the wrist at PC7, common palmar digital artery at PC8, the venous network of the dorsum of the hand at LI4, and the dorsal venous network of the wrist and the carpal artery at TE4 (Chen et al., 1996; Long et al., 1999). The humeral and neural responses to the stimulation on these points might regulate the disturbed circulation and eliminate the inflammation of the carpal tunnel through both chemical and circulation kinesic mechanisms.

Furthermore, during the process of LA's development, some researchers explored the possible mechanism of LA therapy. Goldman et al. (1980) observed an anti-inflammatory effect in rheumatoid arthritis, which had a decreased level of circulating immune complexes.

Mester and his colleagues (1982) supported the results. Walker (1983) found that He-Ne laser affected serotonin metabolism and led to a large increase in urinary excretion of 5-hydroxyindoleacetic acid. These studies all suggest that LA therapy can improve inflammation and cause pain relief.

For treatment-resistant CTS, LA treatment has several distinct advantages in comparison with surgical treatment: one of which is fast recovery. Significant improvement of the symptoms has been achieved in the majority of patients after more sessions of LA. LA is safe without any known complications. It is a much less painful procedure than surgery and requires no hospitalization and additional physiotherapy. Therefore, LA is a safe and economic alternative procedure that should be considered before surgical treatment for the treatment of CTS.

Besides, LA treatment may be directly compared not only to the traditional needle acupuncture, but also to electrical, transcutaneous electrical nerve stimulation (TENS) as is frequently used. LA has the advantages over these treatments of being aseptic, hygienic, non-invasive, painless, easy to accept, easy to operate, and free of side effects.

In conclusion, this study demonstrated an effective protocol of using LA for treatment-resistant idiopathic CTS. LA therapy has the potential to be an effective alternative to surgery and pharmaceutical treatment for many diseases.

CHAPTER 5 CONCLUSIONS

5.1 An Experiment to Investigate the Effects of Laser Acupuncture on Normal Subjects

In this experiment, a diode visible red laser (power density 0.107 W/cm^2) was applied to stimulate four acupuncture points including PC6, PC7, PC8, and LI4 daily over a 10-day period. The effect of the treatment was that LA caused the nerve conduction velocities (including MNCV, anti-SNCV, and ortho-SNCV) to decrease significantly. Detailed conclusions are listed below:

- There were significant differences between measurements of the velocity immediately after the LA application and 30 minutes later for all the three parameters, which were from 56.31 ± 2.80 in MNCV, 58.23 ± 3.64 in anti-SNCV, and 57.54 ± 3.00 in ortho-SNCV to 54.69 ± 2.63 in MNCV, 56.42 ± 3.77 in anti-SNCV and 55.96 ± 3.52 in ortho-SNCV respectively. The results indicated that the effect after 30 minutes of laser acupuncture application was stronger than the immediate effect.
- After applying LA for 10 days, the final nerve conduction velocities had decreased significantly for all the three parameters in comparison to the baseline. In detail, the baselines were 59.84 ± 3.36 in MNCV, 59.66 ± 3.58 in anti-SNCV, and 58.93 ± 3.02 in ortho-SNCV, and the final nerve conduction velocities were 55.33 ± 2.83 in MNCV, 56.17 ± 4.23 in anti-SNCV and 55.72 ± 3.94 in ortho-SNCV.

5.2 An Experiment to Investigate the Effects of Laser Acupuncture on Patients with Carpal Tunnel Syndrome

In this experiment, the diode visible red laser (power density 0.107 W/cm2) was used to stimulate four acupuncture points including PC7, PC8, TE4, and LI4 daily. The effect of the treatment was that LA caused a significant improvement in patients with CTS. Detailed conclusions are listed below:

- Compare to the placebo group, there were significant improvements caused by LA treatment in both subjective and objective presentations.

- From subjective feedback including McGill pain questionnaire (three indices, NWC, PRI, and PPI) and visual analogue scale (VAS), it was clear that patients experienced a significant improvement after one or more sessions of LA treatment. There were reductions of 73.7% in NWC, of 81.2% in PRI, of 73.3% in PPI and of 76.1% in VAS. Besides, these score were reduced to zero in eight hands of six patients.
- From physical evaluations including Phalen's test, grip strength test and pinch strength test indicated significant improvements. After final evaluation, Phalen's test became negative in 10 hands (53%). The results of grip strength test and pinch strength test indicated that the strength increased significantly after the laser acupuncture treatment.
- With the exception of NCSs, the other evaluations indicated that LA therapy caused a significant improvement in patients after just one session. All evaluations indicated that two or more sessions of LA treatment caused patient's conditions to improve more significantly.
- In this study of NCSs in patients, only the MNCV test indicated that LA therapy increased the MNCV significantly. Based on a linear model for NCSs, along with three experimental sessions, both the increasing trend of motor nerve conduction velocity decreasing and the trend of sensory nerve conduction velocity increasing were found.
- There were not any inconveniences during the treatment. There were no side effects or complications following this treatment either.

CHAPTER 6 LIMITATIONS AND FUTURE WORK

6.1 Limitation of the Study

As in many other research studies, there are inevitable limitations to the current study. Two of these are briefly discussed below.

First, although statistical analyses were performed in both experiments on normal subjects and on patient subjects, the sample sizes of the current study were small (18 normal subjects and 12 patient subjects). The experiments involving the patients especially used a rather small sample size that makes it difficult to reach any stronger conclusions about the results.

Second, the follow-up to the experiments on the patient subjects was conducted through telephone interviews. Although the researcher collected subjective data from every patient, no objective data could be collected. There were two follow-up visits carried out in this study. However, clinically, the patient would be observed for a longer term, for example one year. In this study, it was difficult to carry out a clinical follow-up due to the limitations of time and financial factor.

6.2 Recommendations for Future Work

A number of recommendations for further works that is related to the current study are proposed here. First of all, it is clear that much research needs to be done toward setting up a complete protocol system for LA therapy.

A hypothesis can be put forward for continuous wave laser or pulsed wave laser in the LA operation. The continuous wave irradiation LA has the same effect as the retaining needle during traditional acupuncture therapy. Also, pulsed wave LA causes a special effect that is essentially the same as that caused by the basic manipulative techniques involved in traditional acupuncture, namely lifting and thrusting. However, is it possible for other fundamental manipulations of traditional acupuncture therapy, such as twirling or rotating, to be achieved by LA? It is known that laser light contains monochromatic, highly directional, and coherent characteristics. If the angle of LA irradiation is changed slightly within the area of the point location, the effect is similar to that of twirling or rotating. Some

auxiliary manipulations, such as pressing, plucking, scraping, shaking, and flying, are easy to mimic by changing the magnitude of pressure on the probe. All the above hypotheses need to be tested and evaluated by advanced future research.

The selection of an accurate dosage is the most important factor in LA application. In this study, a new set of therapeutic parameters based upon previous studies by other researchers has be used, because no distinct relationship has been demonstrated between the laser light parameters, treatment factors, and the various patients. It is clear that further experimental research is necessary to identify optimal values for accurate treatment parameters.

In the clinical practice of pain relief, there are numerous alternatives to LA therapy. It is the first duty of every doctor to choose the treatment that is most suitable for the patient. It is recommended that more work be done in this field.

Among the many forms of therapy in the medical field, LA is comparatively new. Developing it further in order to benefit human health is a worthwhile aim.

Appendix I: Consent form

CONSENT FORM

I, _____ (name) (I.D. Card # _____), Hereby consent to participate in as a subject for the research entitled "Effects of the laser acupuncture therapy on treating pain". I understand the effect and details of the experimental procedures which have been explained to me.

I understand I have the right to discontinue, with no reasons given, my participation anytime, even during the experiment. I realize that any findings of the study will only be used for research purpose and will be the properties of the Rehabilitation Engineering Centre, The Hong Kong Polytechnic University

Signed _____

Date _____

In Witness_____
( )

Date _____

Appendix II: Standard international nomenclature of the fourteen main meridians

	English Name	Pinyin Name	Alphabetic code
1	Lung Meridian	Shou tai yin fei jing	LU
2	Large Intestine Meridian	Shou yang ming da chang jing	LI
3	Stomach Meridian	Zu yang ming wei jing	ST
4	Spleen Meridian	Zu tai yin pi jing	SP
5	Heart Meridian	Shou shao yin xin jing	HT
6	Small Intestine Meridian	Shou tai yang xiao chang jing	SI
7	Bladder Meridian	Zu tai yang pang guang jing	BL
8	Kidney Meridian	Zu shao yin shen jing	KI
9	Pericardium Meridian	Shou jue yin xin bao jing	PC
10	Triple Energizer Meridian	Shou shao yang san jiao jing	TE
11	Gallbladder Meridian	Zu shao yang dao jing	GB
12	Liver Meridian	Zu jue yin gan jing	LR
13	Governor Vessel	Du mai	GV
14	Conception Vessel	Ren mai	CV

Appendix III: Raw data of the reliability test of dynamomter (kg)

	1st					2nd (30min)				
	1st	2nd	3th	Mean	SD	1st	2nd	3th	Mean	SD
1 L	24.0	23.2	25.2	24.13	1.01	24.8	24.6	22.8	24.07	1.10
R	27.2	25.4	24.8	25.80	1.25	25.0	25.6	27.8	26.13	1.47
2 L	34.6	33.9	32.0	33.50	1.35	36.2	31.0	32.0	33.07	2.76
R	37.3	33.8	32.4	34.50	2.52	32.0	35.8	35.8	34.53	2.19
3 L	40.4	41.2	42.0	41.20	0.80	41.4	39.6	40.4	40.47	0.90
R	38.2	38.8	36.8	37.93	1.03	39.0	36.6	37.8	37.80	1.20
4 L	26.2	27.8	27.0	27.00	0.80	26.2	27.8	28.0	27.33	0.99
R	26.0	27.0	26.4	26.47	0.50	24.8	27.0	26.4	26.07	1.14
5 L	22.4	19.9	19.9	20.73	1.44	25.0	19.0	19.2	21.07	3.41
R	27.2	25.0	25.0	25.73	1.27	27.2	24.0	25.0	25.40	1.64
6 L	29.8	26.6	33.2	29.87	3.30	30.0	26.6	32.0	29.53	2.73
R	28.0	28.8	32.2	29.67	2.23	29.0	28.4	30.2	29.20	0.92
7 L	19.2	18.6	20.0	19.27	0.70	21.6	20.6	18.0	20.07	1.86
R	17.8	17.0	17.6	17.47	0.42	17.8	16.2	17.6	17.20	0.87
8 L	31.0	32.0	33.2	32.07	1.10	32.0	31.9	31.6	31.83	0.21
R	31.4	31.6	30.0	31.00	0.87	33.2	30.4	32.2	31.93	1.42
9 L	34.4	32.0	34.6	33.67	1.45	30.4	34.8	34.1	33.10	2.36
R	38.4	34.2	35.2	35.93	2.19	36.4	37.9	36.0	36.77	1.00
10 L	42.4	40.2	36.4	39.67	3.04	41.4	42.0	37.2	40.20	2.62
R	42.0	42.2	40.4	41.53	0.99	40.2	42.0	39.4	40.53	1.33

Appendix IV: Raw data of the reliability test of pinch gauge (kg)

	1st					2nd (30min)				
	1st	2nd	3th	Mean	SD	1st	2nd	3th	Mean	SD
1 L	6.5	6.7	6.5	6.57	0.12	6.5	6.3	6.4	6.40	0.10
R	7.0	7.4	7.6	7.33	0.31	7.5	7.6	7.6	7.57	0.06
2 L	8.5	9.0	8.6	8.70	0.26	9.3	8.7	8.7	8.90	0.35
R	8.8	8.9	8.1	8.60	0.44	8.3	7.9	8.3	8.17	0.23
3 L	8.2	8.2	7.9	8.10	0.17	8.2	7.9	7.7	7.93	0.25
R	7.9	8.3	8.0	8.07	0.21	8.2	8.2	8.1	8.17	0.06
4 L	9.1	9.2	8.9	9.07	0.15	9.2	9.2	9.3	9.23	0.06
R	8.8	8.5	8.8	8.70	0.17	8.3	8.8	9.0	8.70	0.36
5 L	5.2	4.7	5.5	5.13	0.40	5.3	4.9	5.2	5.13	0.21
R	5.8	5.4	5.5	5.57	0.21	5.7	5.7	5.5	5.63	0.12
6 L	6.1	5.9	5.7	5.90	0.20	6.2	6.1	5.8	6.03	0.21
R	7.6	7.2	7.8	7.53	0.31	7.6	6.8	7.2	7.20	0.40
7 L	6.4	6.9	6.9	6.73	0.29	6.3	6.5	7.5	6.77	0.64
R	5.7	5.9	5.8	5.80	0.10	6.3	6.5	6.2	6.33	0.15
8 L	6.1	5.7	6.4	6.07	0.35	6.3	5.7	6.2	6.07	0.32
R	6.7	6.8	6.7	6.73	0.06	6.7	6.3	6.6	6.53	0.21
9 L	8.9	8.3	8.9	8.70	0.35	8.4	8.8	8.9	8.70	0.26
R	10.6	10.1	10.5	10.40	0.26	9.2	10.4	10.3	9.97	0.67
10 L	9.7	9.7	10.6	10.00	0.52	9.7	10.6	10.3	10.20	0.46
R	10.2	10.3	10.5	10.33	0.15	10.6	10.2	10.7	10.50	0.26

Appendix V: Raw data of nerve conduction velocities (m/s) on normal subjects' LA hands

		No-1	No-2	No-3	No-4	No-5	No-6	No-7	No-8	No-9	No-10	No-11	No-12	No-13	No-14	No-15	No-16	No-17	No-18
MNCV	Pre-test-1	64	64	60	60	61	59	62	63	59	59	51	63	56	61	62	59	55	62
	Pre-test-2	64	64	60	61	60	58	62	63	59	59	51	63	56	60	62	59	55	62
	Day1-1	62	60	57	59	56	55	58	60	57	59	48	61	54	58	56	57	54	58
	Day1-2	61	58	55	58	55	53	55	58	55	58	44	58	53	55	54	54	52	55
	Day5-1	59	58	53	56	53	52	56	59	55	56	50	60	53	54	58	57	53	57
	Day5-2	56	56	51	57	52	52	57	58	55	53	49	57	51	53	55	57	54	55
	Day10-1	57	54	53	55	52	51	59	59	61	55	51	61	55	59	59	57	55	61
	Day10-2	55	53	57	56	52	50	57	59	56	55	50	58	53	58	58	56	54	59
Anti-SNCV	Pre-test-1	58	58	58	61	59	58	59	58	56	47	55	63	61	60	64	69	59	62
	Pre-test-2	55	56	58	59	59	59	59	58	58	59	55	63	60	58	63	69	59	62
	Day1-1	55	57	56	59	53	58	59	50	55	59	49	61	58	58	63	67	64	59
	Day1-2	55	55	55	60	53	55	57	53	53	59	48	60	52	49	62	65	61	58
	Day5-1	59	55	55	62	58	59	57	58	58	57	56	60	57	54	61	67	63	58
	Day5-2	57	55	57	58	56	57	57	58	58	57	52	59	54	51	60	66	62	56
	Day10-1	54	55	56	58	58	57	57	53	61	57	54	64	58	58	65	65	61	63
	Day10-2	55	50	57	55	54	56	55	52	57	56	47	60	53	57	63	62	60	62
Ortho-SNCV	Pre-test-1	59	60	60	61	59	55	58	58	58	48	55	61	61	60	65	64	62	61
	Pre-test-2	54	59	60	60	58	56	57	58	57	53	55	61	61	56	64	64	61	62
	Day1-1	55	57	56	61	54	57	59	50	54	60	49	60	58	57	62	63	63	58
	Day1-2	55	54	57	58	54	55	58	53	52	54	48	59	52	48	62	63	62	57
	Day5-1	56	55	57	61	60	54	60	59	59	59	54	58	57	54	62	63	61	58
	Day5-2	56	52	57	59	59	54	62	57	57	59	51	57	53	51	61	64	61	56
	Day10-1	55	53	52	60	60	54	59	52	61	57	54	60	58	58	62	62	58	63
	Day10-2	53	51	54	58	58	54	57	50	58	52	48	58	54	57	62	59	58	62

Appendix VI: Raw data of nerve conduction velocities (m/s) on normal subjects' controlled hands

		No-7	No-8	No-9	No-10	No-11	No-12	No-13	No-14	No-15	No-16	No-17	No-18
MNCV	Pre-test-1	61	61	57	54	56	61	52	60	55	56	61	60
	Pre-test-2	60	60	57	54	56	61	53	60	56	56	61	61
	Day1-1	60	60	57	54	56	61	52	59	55	56	61	61
	Day1-2	60	60	57	55	56	61	52	58	55	55	61	61
	Day5-1	60	60	57	55	56	61	52	60	55	56	61	60
	Day5-2	60	60	57	54	56	61	52	60	55	56	59	60
	Day10-1	61	60	56	53	56	61	52	61	55	56	60	61
	Day10-2	60	61	57	54	56	61	52	60	56	56	61	61
Anti-SNCV	Pre-test-1	59	57	53	47	55	62	61	61	64	63	63	60
	Pre-test-2	59	57	56	55	55	62	61	59	64	65	61	60
	Day1-1	58	57	53	55	54	62	60	60	64	62	62	60
	Day1-2	59	54	54	59	52	62	58	58	64	63	63	60
	Day5-1	59	56	57	59	55	60	59	60	64	63	61	60
	Day5-2	58	54	57	58	54	62	59	59	62	63	60	58
	Day10-1	59	57	57	59	55	62	60	60	65	62	61	59
	Day10-2	59	56	57	57	55	62	60	60	63	62	61	59
Ortho-SNCV	Pre-test-1	58	56	56	49	53	61	60	60	62	61	60	60
	Pre-test-2	58	54	57	56	53	62	61	58	62	61	60	60
	Day1-1	58	54	54	56	53	62	58	60	61	61	60	60
	Day1-2	58	55	54	58	53	61	58	60	61	59	60	60
	Day5-1	58	56	55	57	53	60	59	58	62	61	60	60
	Day5-2	59	56	57	55	53	59	59	57	62	63	59	60
	Day10-1	58	56	56	56	54	62	59	60	63	60	59	61
	Day10-2	58	51	56	55	52	61	59	60	62	59	60	61

Appendix VII: Raw data on patients in Session I

		No-1	No-2	No-3	No-4	No-5	No-6	No-7	No-8	No-9	No-10	No-11	No-12
VAS	LA: pre-I	9.0	3.0	4.5	4.5	10.0	5.5	3.0	6.0	5.0	5.0	6.0	7.0
	LA: post-I	5.0	1.5	3.5	0.0	7.0	1.0	1.0	3.5	3.0	3.5	3.0	4.0
	Placebo : pre-I	5.0	1.5	2.5	4.5	5.0	3.0	3.0	2.0	6.0	3.5	5.0	1.0
	Placebo : post-I	5.0	1.0	2.0	4.0	4.5	2.0	2.0	2.5	5.0	3.0	3.0	1.0
PQ-NWC	LA: pre-I	10	9	10	12	16	9	8	10	7	14	9	10
	LA: post-I	9	6	7	0	14	2	2	2	4	9	5	9
	Placebo : pre-I	11	5	4	11	12	8	8	5	7	13	7	2
	Placebo : post-I	12	6	5	11	14	7	6	3	8	10	7	3
PQ-PRI	LA: pre-I	24	10	25	17	58	17	13	23	15	34	22	18
	LA: post-I	15	8	10	0	38	3	2	3	7	12	6	14
	Placebo : pre-I	20	6	5	17	17	9	11	7	16	17	10	3
	Placebo : post-I	21	7	13	17	34	9	6	10	16	12	8	4
PQ-PPI	LA: pre-I	4	1	3	1	5	2	1	2	3	3	2	3
	LA: post-I	2	1	1	0	3	1	1	1	1	1	1	1
	Placebo : pre-I	2	1	1	1	1	1	1	1	3	2	1	1
	Placebo : post-I	2	1	1	1	1	1	1	1	3	1	1	1

(Cont'd)

Grip Test (kg)	LA: pre-I	12.0	16.3	11.6	21.4	10.9	14.5	24.6	28.3	19.2	18.2	24.1	13.0
	LA: post-I	12.6	15.9	14.9	20.9	9.6	15.6	29.3	30.9	19.6	18.2	24.9	16.8
	Placebo : pre-I	12.0	16.3	17.8	17.9	18.3	15.3	25.6	25.7	18.8	17.9	23.7	16.8
	Placebo : post-I	12.9	12.8	18.0	17.1	16.0	16.5	29.0	26.3	19.1	16.6	24.1	17.7
Pinch Test (kg)	LA: pre-I	5.6	3.3	3.7	6.2	5.1	3.5	6.0	9.4	6.0	5.3	7.1	5.5
	LA: post-I	5.8	3.2	4.7	6.4	5.1	4.4	6.9	9.4	6.3	5.5	6.9	5.1
	Placebo : pre-I	5.8	3.2	5.0	6.0	5.2	3.6	6.9	8.6	6.6	4.9	7.9	6.4
	Placebo : post-I	6.1	3.4	5.2	6.3	5.2	4.3	6.9	9.2	6.8	5.4	7.6	7.1
Phalen's Test (s)	LA: pre-I	15	13	18	>60	24	20	15	>60	19	50	24	23
	LA: post-I	27	>60	25	>60	17	28	16	>60	39	58	>60	30
	Placebo : pre-I	57	39	30	>60	20	19	13	>60	22	46	37	46
	Placebo : post-I	42	40	32	>60	25	11	14	>60	26	40	40	45

(Cont'd)

LA Group

		No-1(R)	No-2(R)	No-3(L)	No-4(R)	No-5(R)	No-6(R)	No-7(L)	No-8(R)	No-9(L)	No-10(L)	No-11(L)	No-12 (L)
MNCV (m/s)	Pre-test-1	23	49	51	34	40	48	57	52	46	54	56	52
	Pre-test-2	23	49	51	35	40	48	57	53	46	54	56	49
	Day1-1	18	53	54	43	40	54	59	56	49	59	58	56
	Day1-2	20	50	53	47	41	52	57	55	48	59	58	51
	Day5-1	27	52	56	51	35	59	61	58	51	60	63	42
	Day5-2	35	51	55	50	39	55	62	58	52	58	58	53
	Day10-1	24	53	58	51	30	58	60	57	44	60	59	54
	Day10-2	35	50	56	52	28	55	59	55	43	56	58	52
Anti-SNCV (m/s)	Pre-test-1	Nil	45	Nil	Nil	Nil	57	47	44	39	60	52	31
	Pre-test-2	Nil	46	Nil	Nil	25	56	47	45	39	60	55	31
	Day1-1	Nil	48	48	34	Nil	55	50	49	41	64	58	33
	Day1-2	Nil	47	49	34	Nil	55	46	47	36	62	57	32
	Day5-1	Nil	51	50	Nil	Nil	57	48	48	34	61	57	34
	Day5-2	Nil	49	46	Nil	Nil	56	48	46	32	58	57	36
	Day10-1	Nil	46	51	Nil	Nil	56	50	42	28	60	59	33
	Day10-2	Nil	44	48	27	Nil	56	47	42	29	58	57	32
Ortho-SNCV (m/s)	Pre-test-1	Nil	46	Nil	Nil	Nil	48	39	44	34	61	54	32
	Pre-test-2	Nil	46	Nil	Nil	Nil	47	46	44	34	60	57	31
	Day1-1	Nil	48	Nil	Nil	Nil	46	48	44	34	62	57	34
	Day1-2	Nil	42	41	Nil	Nil	45	45	46	32	62	56	31
	Day5-1	Nil	50	Nil	Nil	Nil	50	50	46	33	62	57	38
	Day5-2	Nil	49	Nil	Nil	Nil	48	48	44	32	60	55	34
	Day10-1	Nil	46	Nil	Nil	Nil	50	48	42	27	62	59	35
	Day10-2	Nil	44	Nil	Nil	Nil	44	45	42	26	61	56	33

(Cont'd)

Placebo Group

		No-1(L)	No-2(L)	No-3(R)	No-4(L)	No-5(L)	No-6(L)	No-7(R)	No-8(L)	No-9(R)	No-10(R)	No-11(R)	No-12(R)
MNCV (m/s)	Pre-test-1	43	53	49	61	43	57	55	59	46	60	52	58
	Pre-test-2	43	52	49	62	44	56	57	60	46	60	52	58
	Day1-1	43	51	49	63	44	55	56	60	46	60	52	58
	Day1-2	44	51	49	62	44	55	55	59	46	60	52	57
	Day5-1	44	52	49	63	45	57	55	60	46	60	54	58
	Day5-2	44	52	49	63	45	56	55	59	42	60	54	58
	Day10-1	43	52	49	63	44	56	61	59	42	60	52	58
	Day10-2	43	52	49	63	44	56	56	59	42	60	52	58
Anti-SNCV (m/s)	Pre-test-1	Nil	47	43	46	41	51	53	54	Nil	63	56	48
	Pre-test-2	Nil	48	44	47	42	50	Nil	54	Nil	63	56	48
	Day1-1	Nil	46	44	47	42	49	49	55	Nil	63	56	48
	Day1-2	Nil	46	44	47	42	49	51	55	Nil	62	56	47
	Day5-1	Nil	46	44	48	42	50	53	55	Nil	63	56	54
	Day5-2	Nil	46	44	45	41	50	49	54	Nil	62	56	54
	Day10-1	Nil	47	45	45	41	51	53	48	Nil	63	56	53
	Day10-2	Nil	48	44	46	41	50	51	49	Nil	62	56	52
Ortho-SNCV (m/s)	Pre-test-1	Nil	50	39	45	42	50	52	53	Nil	62	57	50
	Pre-test-2	Nil	48	35	46	42	50	50	54	Nil	62	56	48
	Day1-1	Nil	48	36	47	41	49	50	54	Nil	62	56	47
	Day1-2	Nil	48	39	47	42	46	48	52	27	62	56	47
	Day5-1	Nil	50	Nil	46	42	49	53	54	26	62	56	51
	Day5-2	Nil	50	46	47	42	50	52	53	27	61	56	52
	Day10-1	Nil	48	Nil	45	41	50	51	51	Nil	62	55	51
	Day10-2	Nil	49	Nil	44	41	50	48	50	25	62	55	50

Appendix VIII: Raw data on patients in Session II

			No-1	No-2	No-3	No-5	No-7	No-8	No-12
VAS	Left	pre-II	5	8.0	3	3	2	2	4
	Left	post-II	4	1.5	1.5	0	0	0	1
	Right	pre-II	5	1.5	2	4.5	2	2	1
	Right	post-II	4	1.5	1	3	0	0	0
PQ-NWC	Left	pre-II	13	8	7	11	5	3	10
	Left	post-II	9	4	5	0	0	0	6
	Right	pre-II	11	9	6	9	6	2	3
	Right	post-II	10	4	2	7	0	0	0
PQ-PRI	Left	pre-II	25	18	14	15	6	10	21
	Left	post-II	11	5	12	0	0	0	7
	Right	pre-II	20	9	15	12	7	2	4
	Right	post-II	15	6	3	10	0	0	0
PQ-PPI	Left	pre-II	2	2	1	1	1	1	1
	Left	post-II	1	1	1	0	0	0	1
	Right	pre-II	1	1	1	1	1	1	1
	Right	post-II	1	1	1	1	0	0	0

(Cont'd)

Grip Test (kg)	Left	pre-II	14.2	14.8	16.7	20.1	28.9	30.3	15.5
	Left	post-II	15.9	12.1	18.6	17.0	29.7	32.0	18.0
	Right	pre-II	14.1	16.6	18.4	14.7	28.6	30.0	15.4
	Right	post-II	15.4	14.0	16.6	13.3	30.1	35.1	16.8
Pinch Test (kg)	Left	pre-II	3.4	4.4	5.2	6.1	7.1	9.4	5.5
	Left	post-II	3.6	3.3	6.0	5.9	7.6	9.8	5.8
	Right	pre-II	2.9	4.3	5.6	6.0	7.7	9.4	7.2
	Right	post-II	3.4	3.5	5.7	5.8	8.4	9.7	7.6
Phalen's Test (s)	Left	pre-II	29	35	20	44	22	>60	21
	Left	post-II	35	>60	35	27	35	>60	31
	Right	pre-II	27	22	40	21	22	>60	33
	Right	post-II	35	>60	>60	19	32	>60	>60

(Cont'd)

		No-1		No-2		No-3		No-5		No-7		No-8		No-12	
		Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right
MNCV (m/s)	Pre-test-1	45	40	55	49	51	49	40	35	59	63	61	58	42	54
	Pre-test-2	49	39	55	50	51	50	41	31	59	63	62	58	48	52
	Day1-1	48	36	58	53	54	53	41	36	58	59	65	59	50	53
	Day1-2	48	36	57	51	53	51	39	38	58	60	65	57	51	54
	Day5-1	45	40	55	54	53	54	43	42	55	61	62	57	49	56
	Day5-2	45	41	50	52	52	52	40	41	57	56	61	56	51	59
	Day10-1	48	42	55	58	54	54	45	35	57	58	59	55	52	54
	Day10-2	52	44	53	56	53	52	43	41	56	58	59	55	54	55
Anti-SNCV (m/s)	Pre-test-1	Nil	Nil	48	50	46	46	36	Nil	49	55	56	48	34	45
	Pre-test-2	Nil	Nil	48	50	47	46	37	Nil	50	56	56	48	34	53
	Day1-1	Nil	Nil	47	50	48	47	36	Nil	53	57	58	49	39	51
	Day1-2	Nil	Nil	44	49	47	46	36	20	52	53	57	48	35	49
	Day5-1	Nil	Nil	43	47	47	Nil	41	Nil	57	55	60	51	50	52
	Day5-2	Nil	Nil	41	48	47	48	41	Nil	53	58	59	49	32	55
	Day10-1	Nil	Nil	49	50	52	48	41	Nil	54	57	59	51	37	54
	Day10-2	Nil	Nil	44	46	50	46	40	Nil	53	57	57	51	41	53
Ortho-SNCV (m/s)	Pre-test-1	Nil	Nil	47	46	Nil	43	37	Nil	48	56	56	45	34	46
	Pre-test-2	Nil	Nil	48	49	51	45	37	Nil	49	56	56	45	33	50
	Day1-1	Nil	Nil	45	49	40	Nil	36	Nil	52	52	59	45	40	50
	Day1-2	Nil	Nil	48	48	40	Nil	36	Nil	50	52	56	45	35	48
	Day5-1	Nil	Nil	40	47	Nil	Nil	40	Nil	52	56	59	48	33	50
	Day5-2	Nil	Nil	39	46	40	46	39	Nil	50	55	58	47	33	53
	Day10-1	Nil	Nil	49	48	Nil	47	40	21	51	56	57	49	32	52
	Day10-2	Nil	Nil	44	45	Nil	35	38	28	50	54	55	48	38	50

Appendix IX: Raw data on patients in Session III

			No-1	No-2	No-3	No-5
VAS	Left	pre-III	4	1.0	2	2
	Left	post-III	4	2.0	1	0
	Right	pre-III	3.5	2.0	-	3
	Right	post-III	3	0.0	-	0
PQ-NWC	Left	pre-III	9	6	3	2
	Left	post-III	9	3	0	0
	Right	pre-III	9	5	-	10
	Right	post-III	6	0	-	0
PQ-PRI	Left	pre-III	14	8	4	2
	Left	post-III	12	6	0	0
	Right	pre-III	12	4	-	20
	Right	post-III	9	0	-	0
PQ-PPI	Left	pre-III	1	1	1	1
	Left	post-III	1	1	0	0
	Right	pre-III	1	1	-	1
	Right	post-III	1	0	-	0

(Cont'd)

Grip Test (kg)	Left	pre-III	14.2	13.9	18.7	20.9
	Left	post-III	15.6	17.7	18.6	19.7
	Right	pre-III	14.7	16.3	-	13.2
	Right	post-III	16.0	17.5	-	15.7
Pinch Test (kg)	Left	pre-III	3.5	3.8	5.9	6.0
	Left	post-III	3.6	4.0	5.8	6.3
	Right	pre-III	3.5	3.4	-	5.5
	Right	post-III	3.4	4.0	-	5.6
Phalen's Test (s)	Left	pre-III	>60	59	>60	20
	Left	post-III	>60	>60	>60	25
	Right	pre-III	>60	29	-	11
	Right	post-III	>60	52	-	21

(Cont'd)

		No-1		No-2		No-3		No-5	
		Left	Right	Left	Right	Left	Right	Left	Right
MNCV (m/s)	Pre-test-1	45	32	62	51	53	-	42	31
	Pre-test-2	43	33	62	51	53	-	42	38
	Day1-1	43	34	63	48	56	-	42	40
	Day1-2	44	37	62	47	55	-	41	40
	Day5-1	43	31	59	52	56	-	43	31
	Day5-2	45	38	55	51	54	-	41	32
	Day10-1	48	35	55	53	58	-	46	33
	Day10-2	46	35	56	53	56	-	44	33
Anti-SNCV (m/s)	Pre-test-1	Nil	Nil	46	45	48	-	41	Nil
	Pre-test-2	Nil	Nil	47	44	50	-	39	Nil
	Day1-1	Nil	Nil	48	50	52	-	40	Nil
	Day1-2	Nil	Nil	42	42	49	-	40	Nil
	Day5-1	Nil	Nil	53	51	50	-	45	22
	Day5-2	Nil	Nil	49	48	51	-	39	34
	Day10-1	Nil	Nil	52	50	53	-	37	44
	Day10-2	Nil	Nil	51	49	50	-	37	43
Ortho-SNCV (m/s)	Pre-test-1	Nil	Nil	49	44	47	-	39	Nil
	Pre-test-2	Nil	Nil	48	44	48	-	39	Nil
	Day1-1	Nil	Nil	48	44	48	-	40	Nil
	Day1-2	Nil	Nil	46	44	48	-	40	Nil
	Day5-1	Nil	Nil	53	50	50	-	40	Nil
	Day5-2	Nil	Nil	48	47	50	-	38	Nil
	Day10-1	Nil	Nil	52	50	51	-	38	Nil
	Day10-2	Nil	Nil	51	50	50	-	37	Nil

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