



Review Article

Photobiomodulation of Acupoints on Standardized Therapeutic Protocols: An Example of Successful Integration between Eastern and Western Medicine

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Abstract

Acupuncture has not yet gained uniform acceptance among Western medicine (WM) practitioners, despite its increasing use in healthcare facilities and its growing popularity with the general public to treat a wide range of clinical conditions. Anyone who works with acupuncture or traditional Chinese medicine (TCM) is acutely aware of the complexity of achieving a true integration of these Eastern practices into Western medicine, a process hampered by the difficulty in finding a unique biological explanation for the established efficacy of TCM therapies. Despite such difficulty, acupuncture application is expanding, and clinical evidence is growing rapidly. We submit that it is just about time to start integrating the two worlds bridging the gap between them. **Object:** Our work was therefore aimed at proposing a combination of the western criterion of applying standardized therapeutic protocols and of the eastern principle of restoring the healthy energy flow throughout the body by stimulating specific sequences of well-known acupuncture points. **Methods:** We first searched PubMed and found 43,062 studies involving acupuncture, mostly published following WWII. Of these, several thousands were reviews and dealt with almost all fields of human and veterinary medicine. In our opinion these can constitute solid evidence of the possibility of a fruitful integration between western and eastern medicine. We then propose a summary of the main studies supporting the acupunctural mechanism-of-action by the western scientific method. On the other hand, a more recent innovation, rapidly growing in popularity, involves the use of low light level lasers or photobiomodulation devices to perform acupunctural stimulation. Such devices, which emit levels of power/energy well under those of conventional laser therapy devices, are overcoming the issues of needles inflexion (both of legal concern and of safety of the patient). Applying a novel internationally patented photobiomodulation device (Libralux) we proposed standardized protocols of stimulation based on a sort of “greatest common factor” principle from the different TCM protocols that could be proposed for

each specific clinical conditions gaining satisfactory outcomes. **Results:** we submit that standardized acupunctural protocols using photobiomodulation devices that have been proven to grant similar effects might be applied by clinical staff persons despite not being traditional acupuncture practitioners. Such an integration would not only be beneficial for patients, but also for a mutual understanding of the two medical schools, in the past considered alternatives, currently seen as complementary, and hopefully as one single school in the not-too-distant future.

Keywords: Western medicine; Traditional Chinese medicine; Acupuncture; Laseracupuncture; Photobiomodulation

Introduction

The rapid rise in popularity of traditional Chinese medicine (TCM) and of acupuncture, one of its branches, in the Western world following the end of WWII is reflected in the rapid growth of TCM schools, a growth which has gone hand-in-hand with the standardization of common criteria for training courses, and which is closely related to the demand for this type of healthcare by the general public. The exponential growth of papers about acupuncture applications indexed in PubMed is another clear sign of the increasing attention paid to TCM by both the Eastern and Western schools of medicine alike. The very different approaches to healthcare by Western medicine and TCM is probably the main reason that TCM in the West was initially considered an alternative medicine, only later becoming recognised as a form of complementary medicine, and statements and indications from the WHO have certainly played an essential role in narrowing the gap between the two schools of medicine. This study proposes a synergistic role of the two approaches, with the adoption of acupuncture based treatment protocols in standard WM clinical practice as a possible starting point, and the ability of non-invasive acupuncture-like stimulators to substantially reduce the contraindications related to needle insertion, especially in sensitive areas (periocular spaces, nervous plexuses, locations at risk of pulmonary or visceral parenchymal perforation) will certainly help such an approach gain wider acceptance. Based on our experiences, we believe that a sort of “greatest common factor” TCM acupuncture protocol can be adopted, one which treats only those acupuncture points effective for the various conditions linked to a particular dysfunction. This is certainly the case for many of the WM clinical conditions where acupuncture has demonstrated its effectiveness - if not for all - and the skilled acupuncturist will be able to extend such protocols for a “personalized” therapeutic approach, based on the diagnostic indications of TCM. Besides being beneficial to patients, this approach potentially offers a powerful tool for promoting a harmonic integration between TCM and WM.

Acupuncture and the West

The attention of the Western world to acupuncture and traditional Chinese medicine is continuously growing, reflected

by the immense number of training opportunities, the increasing number of therapists, and the enormous body of scientific literature. The consensus is that Western and traditional Chinese medicine may be complementary; TCM has anticipated modern concepts of a holistic approach to disease and the concept of personalized medicine by millennia, and TCM - acupuncture in particular - are currently used in tandem with WM in many Eastern and Western healthcare facilities for the management of complex conditions, such as chronic pain. The contraindications associated with acupuncture are modest, and are mostly related to technical issues, such as inappropriate point selection, or with needle insertion itself. However, acupoint stimulation can also be achieved using very low intensity light emissions (laser acupuncture or acupunctural photobiomodulation) [1], thus avoiding these contraindications.

Traditional Chinese medicine has a very ancient history, and it has remained faithful to its principles and alphabet throughout many centuries. Western authorities, such as the National Institute of Health, are focusing on the safety and efficacy of these approaches, and the World Health Organization has included traditional therapies in a global diagnostic compendium [2]. Given the great differences between the languages and methodologies of TCM and WM, it may be difficult to design clinical studies aimed at validating TCM using the WM approach.

In this manuscript we discuss the state of the integration between WM and TCM, considering acupuncture as reference practice, and focus on outlining criteria to further promote this integration. We will first review the principles and history of TCM, followed by a discussion of the Western approaches to TCM teaching and practice, and the state of the scientific validation and clinical application of TCM. Finally, we will examine both the diagnostic and therapeutic aspects of acupuncture, taking inspiration from two very recent papers proposed by Matos et al. [3,4]. Acupuncture is often evaluated based on its therapeutic capabilities only, completely disregarding the diagnostic aspect as intended by TCM, an oversight which creates a further bias when evaluating the efficacy of TCM, since most studies examine TCM therapies from a Western diagnostic standpoint only. Matos et al. discuss the possibility of developing systems to parameterize TCM syndromes using objective measurements and offer several interesting insights into TCM principles. Given the difficulties of translating the diagnostic concepts of TCM to a Western medical framework, we consider this approach to be crucial for an effective

integration of the two medical cultures, since it does not distort TCM principles, seeking instead to translate its concepts into more comprehensible terms.

Our study

We first analysed the PubMed evidence to identify the WM clinical conditions for which acupuncture treatments have been used. We subsequently focused our attention on the history of TCM and the main concepts which form the basis of TCM and acupuncture more specifically, before performing a search to identify studies exploring the “state of the art” of the mechanisms of action (MoA) of acupuncture.

Finally, we explored the possibility of proposing “standardized” sets of application protocols for laser acupuncture, based on our own experiences which involved the use of photobiomodulation at an extremely low level of photobiomodulation (<0.02 mW/cm²), applied over acupuncture points at levels of energy far lower than those currently deemed necessary to produce an acupuncture effect.

The evidence for acupuncture in Western medicine

Browsing PubMed with the query “acupuncture” for the period 01/01/1946 – 30/04/2023 retrieved 43,062 manuscripts on many WM clinical conditions (Table 1).

Table 1: Citations on PubMed by the queries on Acupuncture.			
QUERY	CITES	QUERY	CITES
Acupuncture [AND] mechanism [AND] of action	924	Acupuncture [AND] eye cataract	18
Acupuncture [AND] research [AND] study	12.777	Acupuncture [AND] maculopathy	24
Veterinary [AND] Acupuncture	609	Acupuncture [AND] amblyopia	39
Acupuncture [AND] pain	11.265	Acupuncture [AND] myopia	75
Acupuncture [AND] psychiatry	692	Acupuncture [AND] nystagmus	8
Acupuncture [AND] COPD	194	Acupuncture [AND] vertigo	115
Acupuncture [AND] bronchitis	59	Acupuncture [AND] tinnitus	183
Acupuncture [AND] asthma	618	Acupuncture [AND] arthritis	1.603
Acupuncture [AND] COVID	291	Acupuncture [AND] chronic fatigue syndrome	117
Acupuncture [AND] gynaecological disorders	707	Acupuncture [AND] fibromyalgia	247
Acupuncture [AND] birth [AND] delivery	102	Acupuncture [AND] angina	126
Acupuncture [AND] childbirth	153	Acupuncture [AND] myocardial infarct	151
Acupuncture [AND] uterus	208	Acupuncture [AND] Parkinson disease	430
Acupuncture [AND] vulvodynia	21	Acupuncture [AND] multiple sclerosis	95
Acupuncture [AND] incontinence	233	Acupuncture [AND] lateral amyotrophic sclerosis	38
Acupuncture [AND] diabetes	874	Acupuncture [AND] Alzheimer	476
Acupuncture [AND] diabetic neuropathy	171	Acupuncture [AND] Meniere	21
Acupuncture [AND] chronic constipation	84	Acupuncture [AND] capsulitis	134
Acupuncture [AND] thyroid	149	Acupuncture [AND] fasciitis	65

Acupuncture [AND] hypertension	693	Acupuncture [AND] tendinopathy	177
Acupuncture [AND] arrhythmias	226	Acupuncture [AND] muscle strain	146
Acupuncture [AND] carpal tunnel syndrome	85	Acupuncture [AND] ankle sprain	67
Acupuncture [AND] cerebellar ataxia	11	Acupuncture [AND] knee	1.121
Acupuncture [AND] paraparesis	7	Acupuncture [AND] hip	323
Acupuncture [AND] CMT	15	Acupuncture [AND] low back pain	1.049
Acupuncture [AND] stroke rehabilitation	825	Acupuncture [AND] cervical pain	897
Acupuncture [AND] hemiplegia	204	Acupuncture [AND] cervical vertigo	42
Acupuncture [AND] paraplegia	35	Acupuncture [AND] dizziness	270
Acupuncture [AND] disc herniation	269	Acupuncture [AND] elbow	241
Acupuncture [AND] dry eye	126	Acupuncture [AND] shoulder	638
Acupuncture [AND] retinitis	114	Acupuncture [AND] paediatrics	841
Acupuncture [AND] glaucoma	59	Acupuncture [AND] motor control	485
Total Citations (01/01/1946 - 30/04/2023)			43.062

The growth trend in the yearly number of indexed manuscripts is almost exponential, confirming the ever-growing interest in this branch of TCM, an interest which probably comes from both schools of medicine: TCM practitioners willing to meet the WM criteria for evidence-based medicine, and from WM practitioners open to incorporating TCM into their practice due to its increasing popularity. It is important to stress that WM and TCM vary widely in their approach to the sick person: while WM focuses on “static” evidence, TCM seeks to analyse the “dynamic” flow of energy and its alterations. It goes without saying that the two models should be considered as complementary to one another, as both are probably missing certain aspects of the clinical condition. A brief summary of the basis of TCM and acupuncture will clarify such differences.

A brief introduction to acupuncture – History

The first traces of acupuncture date back to 2,700 years BC (some 5,000 years ago) to the famous *Nei Jing Suwen* (The Yellow Emperor’s Classic of Internal Medicine). The *Nei Jing* consisted of two parts – *Su-Wen*, which detailed the principles of this form of medicine, and *Ling-Chau*, which later developed into the technique known today as acupuncture. Experts believe the original text to have consisted of a summary of expertise and know-how collected over the previous centuries, a hypothesis which moves the origins of acupuncture further back in time.

While the earliest evidence of the *Nei Jing* dates to the 7th century b.C. (a copy of this document was found in a Han

shrine in 1974), the origins of acupuncture proper are generally agreed to coincide with the establishment of the Imperial School of Medicine during the Tang dynasty (607-910 a.D.). It was only in 1206 that a physician named Wang Wei Yi published the first full manuscript and created a small bronze statue showing most of the 365 acupuncture points [5], thus putting the golden age of TCM in the thirteenth century AD during the reign of the Song dynasty.

The history of acupuncture in the West began at the end of the 16th century with the Milanese physician Gerolamo Cardano; subsequent practitioners include the Italian Jesuit missionary Matteo Ricci (1607) and the Dutchman Willem Ten Rhijne (1683).

Some of the most important contributions to acupuncture were made by the French scholar and diplomat George Soulié de Morant, whose 1934 volume formed the starting point for the French traditional Chinese medicine school (J.E.H. Niboyet), however it was only around 1970 that TCM finally began to be practiced throughout Europe.

At the end of the last century, the World Health Organization (WHO) published a report [6] on

- the 28 diseases, symptoms and conditions for which acupuncture has been proved —through controlled trials—to be an effective treatment.
- the 63 diseases, symptoms, and conditions for which the therapeutic effect of acupuncture has been shown, but for which further proof is needed.

- the 9 diseases, symptoms, and conditions for which there are only individual controlled trials reporting some therapeutic effects, but for which acupuncture is worth trying because treatment by conventional and other therapies is difficult.
- the 7 diseases, symptoms and conditions for which acupuncture may be tried provided the practitioner has special modern medical knowledge and adequate monitoring equipment.

The use of acupuncture in veterinary medicine also has a long history, like that of human acupuncture. The earliest veterinary acupuncture text appears to be by Bai Le Zhen Jing (Bai Le's Canon of Veterinary Medicine), written around 650 BC. Other important veterinary acupuncture textbooks include *Basic Techniques for Farmers* by Qi-min Yao Shu, and *A Dissertation on the Treatment of Sick Horses* by Quian Ji Tong-Xuan Lun (1279-1368), describing the treatment of horses using acupuncture and moxibustion. Ancient veterinary acupuncture texts are dedicated to horses, and acupoint charts for cattle, pigs, goats, and chickens appeared later.

Today, the term “veterinary” is applied not only to farm animals and pets, but also to laboratory animals used for research purposes, such as rodents. To the best of our knowledge, the charts and information about acupoints in cats, dogs and laboratory rodents are transposed from human texts, an important aspect to consider when comparing human and veterinary acupuncture as part of a holistic health approach. The strategy of transposing acupoints from humans to animals, not yet experimentally verified, must also be considered when comparing efficacy between different species: indeed, while point maps in humans are based on anatomically defined neuro-vascular sites, these points have not been experimentally confirmed in animals. The main anatomical differences between animals and humans should also be considered in the transposition of certain points, for example the presence of a tail, vestigial or absent digits in different species, or the lack of functional muscles (as the soleus muscle in the dog), all of which are related to different biomechanical characteristics. Another example is the significant difference in skull morphology between different canine species, given the location of important acupuncture points in this area; quadrupedal instead of bipedal gait is another major difference to consider. Transpositional maps used in veterinary acupuncture therefore need to be integrated with further anatomical studies to determine the location and size of the various acupuncture points in the different species.

Brief notes on the principles of TCM

This very brief summary is backed by an immense body of literature [7-8].

Traditional Chinese medicine rejects a static model, considering everything to form part of a flow of energy (termed

Qi in Chinese medicine) which moves between two opposing and complementary forces, known as yin and yang.

According to TCM, Qi and the yin and yang polarities form the basis of the manifested world. Yin and yang attract and integrate with each other, without ever merging and cancelling each other out, in a mutual exchange capable of generating the universe and life as we perceive it.

All aspects of nature, including living beings, all types of energy, and all moments in time, can therefore be traced back to the ever-changing combination of these two forces. Each part forms an energetic relationship with the rest of the whole, in a holistic vision which also includes every vital element, such as blood, breath and secretions, feelings and emotional reactions.

The dynamic harmony between yin and yang causes Qi (often translated as “energy”) to take on different forms, from the densest form of matter (yin) to energy itself (yang), including all intermediate forms such as food which is digested.

In humans, Qi comes from breathing, food, and from the genetic heritage passed on by the parents. Generated by yin and yang, Qi is at the center of all physiological processes. It provides vitality to the organs and functions of the body and transforms and spreads through the network of channels and meridians. To remain healthy, it is important to keep its flow free and in the correct relationship between yin and yang: any alteration of the Qi is a cause and an effect of illness. The ancient founders of TCM also observed that there is never total yin or total yang, a concept expressed by the small circles of opposite colour into the TAO symbol, suggesting also that the two conditions are never static, but alternating with each other – in physiological processes such as breathing, for ex-ample – in the constant cycle of time.

TCM divides internal organs into organs and bowels. Organs are solid and yin, and have the task of transforming, containing, and distributing Qi. The bowels are hollow, yang, and in contact with the outside: they absorb food and liquids and expel waste products. Each organ is paired with a corresponding bowel to form five lodges, symbolically described as wood, fire, earth, metal and water, and each lodge is attributed to a different relationship between yin and yang, one of the six organs and the six viscera (the lodge of fire includes two organs and two bowels), and each form of matter or existing energy. The five elements – also called “movements” to stress their dynamic aspect – interact with each other in continuous cycles of stimulation and self-regulation where they exert reciprocal generation and inhibition effects. Qi flows through 12 main channels, 6 yin and 6 yang, also called meridians. These channels take their name from the organs and bowels, and the body performs well when it is in a state of dynamic balance. The main meridians are flanked by:

- musculotendinous channels, which run parallel to the main channels but closer to the surface of the body.
- the Luo channels, which carry Qi to different areas of the body, forming functional anastomoses between two different main meridians.
- extraordinary meridians which regulate important functions.

The acupuncture channels are connected to the organs (yin) and to the bowels (yang), and their functions are explained using figurative and symbolic terms.

Acupuncture points (a total of 365) are control points on the skin, located on the main channels where the Qi flows. When stimulated, these points exert a specific action and function, producing local and remote effects. This permits the practitioner to control the flow of Qi along the meridian, bring the yin and yang back into balance, and act on the organs and bowels to restore their normal physiological functions. Acupuncture points can be stimulated in various ways, using needles, massage, heat (moxa), laser, a Ma Litang hammer, cupping, micro electric currents and photobiomodulation.

The mechanism of action of acupuncture

The mechanistic paradigm is predominant in Western science and medicine, and numerous studies have been devoted to attempting to understand the MoA of acupuncture (PubMed reports 842 publications from 1946 to today). These studies examine the role of anatomical structures such as the peripheral nervous system, muscles, fascia, and extracellular matrix, but no widespread consensus has yet been reached.

There is a tendency among Western scientists to attribute the efficacy of acupuncture to physiological reflexes. A recent approach combining “functional” and “structural” concepts, however, seems to better explain why stimulations (or “stresses”) can bring about both anatomical and physiological changes. This theory is known as “tensegrity” and refers to the ability of a system to integrate compression and tension to endure modifications under stress, and to regain its original configuration on cessation of the stress [9]. The structures of the body, consisting of bones, tendons and muscles, is an excellent example, but the theory also applies to cell structure, and to the intra and extra-cellular fluids which exert variable pressures on the cell itself [10,11]. For a better understanding of the MoA of acupuncture, see the following references [12-19].

Acupuncture is based on the principle that the stimulation of peripheral points on the surface of the body induces biological effects in organs and tissues deep in the body and distant from the point of stimulation. As already discussed, TCM defines acupoints as localized sites where the meridian energy flows from

the surface tissues and infuses into the deep tissues and visceral organs, although how precisely to translate these metaphysical concepts to the framework of modern biomedical knowledge is a hurdle yet to be overcome. One starting point may be the theories of reflexology, which suggest that needle stimulation may cause an artificial activation of systems which are physiologically or psychologically activated in functional situations [20,21], and functional magnetic resonance imaging has demonstrated a correlation between the electrical stimulation of the acupoints at high or low frequency, the activation of specific brain areas, and the analgesic effect of this stimulation [22]. Imaging techniques have also permitted the formulation of correlative maps between acupoints and the “neuromatrix” of pain pathways [23], as well as confirming correlations between acupoints and specific cortical areas of somatic and/or visceral projection, and between the activation of cortical areas, needle rotation, and direction of rotation [24].

Two models currently explain the initiation of acupuncture signals. According to the more widely studied neurological model, the signals initiated by the needle activation of sensory nerve endings and nerve fibres are trans-mitted to the brain via nervous pathways [25-27]. Both manual and electrical stimulation of acupoints stimulate all four types of nerve fibres (A α , A β , A δ , and C) [28], and the interaction with these different fibres creates a variety of sensory signals in response to needle penetration. During acupuncture stimulation, neuropeptides such as Substance P (SP), calcitonin gene-related peptide (CGRP), vasoactive intestinal polypeptide (VIP) and other vasodilatory mediators (such as adenosine and nitrous oxide) are released from peripheral nerve terminals in the tissues close to the needle through the “axonal reflex”, also increasing local peripheral blood flow [29-31]. Acupuncture or electrical stimulation in certain areas of the body at specific frequencies also facilitates the release of opioid peptides in supraspinal brain areas, such as the medulla oblongata, periaqueductal grey matter, and hypothalamus [32,33].

The second model, involving connective tissue, has emerged in recent years [34], and is based not only on insertion of the needle, but also on its rotation. This rotation causes the connective tissue to wind around the needle, stretching and deforming the collagen fibres, and generating signals via the layers of connective tissue surrounding the muscles, organs, and blood vessels. This produces an active cytoskeletal response by the fibroblasts [35], and a degranulation of mast cells. The mechanisms through which this biomechanical action exerts the therapeutic effects of acupuncture, and if and how the connective and neurological models work in synergy, are currently unclear. Some authors are exploring the “fascial network hypothesis of meridians”, involving an overlap between the channel network described by TCM and the complex neuroanatomical organization of the free ending fibres located in

the membranous layer of the superficial fascia. This transduction of mechanical signals through the connective planes which produces a secondary involvement of neurophysiological mechanisms could theoretically constitute a bridge between ancient TCM principles and the proposed neurophysiological explanation [36].

The question becomes increasingly complex and intriguing if we consider laser acupuncture. Recent reviews and meta-analyses support the efficacy of acupoint stimulation using laser-generated coherent light at low energy density for the treatment of myofascial pain, chronic tension headaches, nausea, and vomiting [37-40]. Notably, while signal initiation in laser acupuncture does not require a microtrauma or biomechanical action on the connective fascia, stimulation must be delivered through the acupoints to exert a therapeutic effect, as also demonstrated by experimental studies [41]. Laser irradiation increases the intracellular concentration of Ca^{++} , probably the most important regulator of cytoskeletal stability, influencing cell stretching and mobility. Laser light exerts a regulatory action on the redox state of the cell, and a close correlation between cell redox state and the actin cytoskeleton has been demonstrated [42]. Mitochondria are anchored to the cytoskeleton and have been found to behave as photo transducers, releasing ROS in response to mechanical stimuli applied to the cytoskeleton [43,44]. We submit that further research should try and explain why the photostimulation of acupuncture points has an almost immediate effect on the soft tissue structure that can be detected, for example, in the comparison between the “thickness” of the flexor/abductor muscles of the thumb while a systemic response is apparent only after at least 5 minutes.

Libralux and low level photobiomodulation

The Libralux photobiomodulation device (Figure 1) performs a stimulation through the brief (20 seconds/each acupoint) emission of a pulse modulated light beam (650 nm wavelength laser with a peak power of 7 mW over an area measuring 10 mm²). Its patented modulation is the logic AND of three square waves for a total duty cycle of 0.25% for a mean irradiance of 0.0175 mW/cm² and a total energy stimulation per acupoint of 0.35 mJ.



Figure 1: Libralux photobiomodulation device.

The device is CE certified as a Class IIa medical device, whose intended use is the treatment of musculoskeletal pain and associated disorders.

The empirical and theoretical development of this device – more than 20 years of R&D activities from the first studies through the first patent (Biolite®) [45] – was the subject of specific indexed communications involving a series of tests on animal models [46,47] as well as on cellular cultures [48,49], in addition to clinical evidence.

The selected pulse modulations combined in Libralux include a low frequency modulation selected from the 12 chromatic semitones of the octave 5.5 thru 11 Hz (one for each meridian) which resonate with the natural frequency of each meridian, and the duty cycle is locked at 50%, therefore the radiated light is “meridian specific”.

Stimulation time has been set at 20 seconds on the basis of our experience, however the operator is free to set a shorter treatment time (recommended for weak or severely impaired elderly patients).

Taking a traditional approach to laser therapy (treatment applied directly to the painful area) as a starting point, we discovered over the course of several steps that treating patients with cervical arthrosis via stimulation of the Yanglingquan acupoint (GB 34) led to a significant improvement in their clinical condition [50] in less than 3 minutes.

The musculoskeletal protocols of Libralux

At that point, with the assistance of qualified acupuncture practitioners, we began to define application protocols for eight main musculoskeletal districts (hand and fingers, wrist, elbow, shoulder, neck and cervical, low back and bowel, knee, ankle and foot). The application starts from the main assisted choices (see Figure 2):

- **Equilibra** is a simple myofascial decontracting protocol,
- **Pain& Dysfunction** includes the protocols to treat eight body districts (fingers, wrist, elbow, shoulder, neck, column and bowel, knees and foot). Specific protocols are provided to treat Fibromialgia, Motor dysfunction and Balance deficit)
- **Cutaneous treatment** includes protocols to treat Scars, Keloids as well as Ulcers and Wounds.
- The acupunctural treatment is providing the 12 frequency tuned stimulations to treat acupuncture points along the twelve meridians.



Figure 2: Libralux protocols.

Having selected the Pain & Dysfunction option the district protocols will be point-by-point indicated at three different zoom levels to provide guidance to the practitioner (see Figure 3).

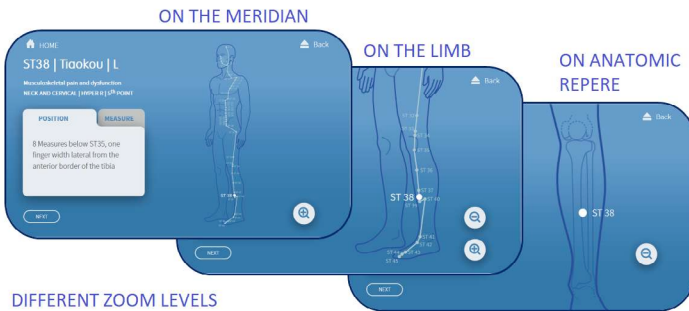


Figure 3: Libralux Treatment point indications.

The acupoints were selected according to the following main criteria:

- The selected points should have no dangerous acupunctural side effects.
- The selected points had to be organized in protocols on a “greatest common factor” basis to treat the most frequent conditions for each of the eight aforementioned areas of the body.

Since a musculoskeletal rehabilitation session would in the majority of cases require either a “sedation” or a “tonification”, two treatment types we defined as hyper (an excess of energy to be drained) or hypo (absorption of energy to compensate for an energy insufficiency) we decided to begin the protocols by bilaterally stimulating the combination of Zusanli (ST36) and Hegu (LI4) for a hyper condition, and Yanglingquan (GB34) and Waiguan (TE5) for a hypo condition.

Other selected points were LV2 Xingjian, LI5 Yangxi; LI11 Quchi; SI3 Houxi; LR2 Xingjian; KI3 Taixi; BL60 Kunlun; ST38 Tiaokou; FM23 Xiyan; BL40 Weizhong and BL66 Tonggu, used in different combinations for the eight different body districts.

The overall logic has been set so that the application protocols begin with the operator selecting either sedation or tonification, and the area of the body to be treated. The appropriate point in the contralateral quadrant, i.e., opposite the upper/lower quadrant where the dysfunction is located, is selected automatically by the device.

The results were very good (80-85% efficacy), and the logic, including an illustrated video guide, was embedded in the Libralux control console which indicates the points to stimulate in the appropriate sequence. Each point is illustrated on the screen, accompanied by a text description. At the end of each stimulation, the operator clicks “Next” to bring up the subsequent point.

Libralux and the full acupuncture application

Following requests from acupuncture practitioners, a function was added to allow radiation at the meridian resonant frequencies for straightforward acupuncture applications. (See Figure 4) Several experiments were then performed, demonstrating the acupunctural effectiveness of Libralux. [51-54]. Besides being of interest to classical acupuncture practitioners, this option has also been welcomed by non-acupuncturists who have seen the positive effects of the proposed protocols, and who are studying the fundamentals of traditional Chinese medicine to better understand its principles, to which many scientists dealing with fascia analysis and treatment also refer to in their work.

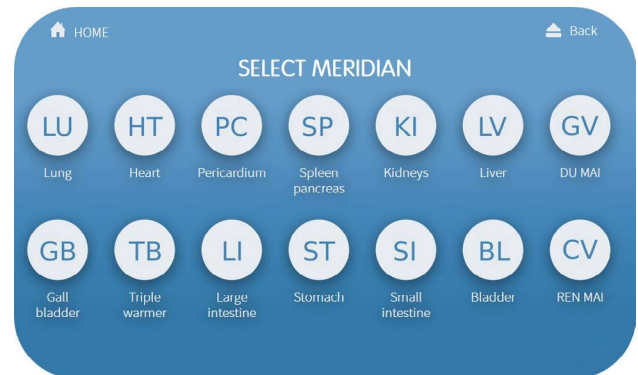


Figure 4: Libralux Acupunctural Application.

Acupuncture protocols in ophthalmology

To illustrate the approach described previously, we will now briefly describe the Libralux stimulation protocols used in two clinical studies: one on amblyopia [51], the other on eye perfusion in wide angle glaucoma [52].

Protocol to treat Amblyopia

The protocol adopted during the first study on amblyopia treating (children aged 3 thru 11 years) is, shown in the following Table 2 and Figure 5.

Table 2: Acupuncture points selected for the amblyopia laser acupuncture protocol.		
Acupoint	Name	Position
EX-HN5	Taiyang	At the temporal dimple and 1 cun behind the midpoint of a line from the lateral end of the eyebrow to the external canthus
BL1	Jing Ming	In a depression, 1 cun above the inner canthus of the eye
LI1	Shang Jang	1 cun posterior to the corner of the nail on the radial side of the index finger
LI4	Hegu	At the dorsum of the hand, and between the first and second metacarpal bones
BL59	Fuyang	3 cun above the site between the Achilles tendon and the lateral malleolus
BL64	Jing Gu	Below the tuberosity of the fifth metatarsal bone at the junction of the red and white skin
BL67	Zhi Yin	0.1 cun posterior to the corner of the nail on the lateral side of the little toe
ST1	Chengqi	Below the pupil, between the eyeball and the infraorbital ridge
GB1	Tong Zi Liao	0.5 cun lateral to the outer canthus of the eye in a depression on the lateral side of the orbit
GB20	Fengchi	In a depression between the upper portion of the sternocleidomastoid muscle and the trapezius, level with GV16
TE23	Sizhukong	In a depression at the lateral end of the eyebrow
SP2	Dadu	On the medial side of the big toe, distal and inferior to the first metatarsal digital joint in a depression at the juncture of the red and white skin

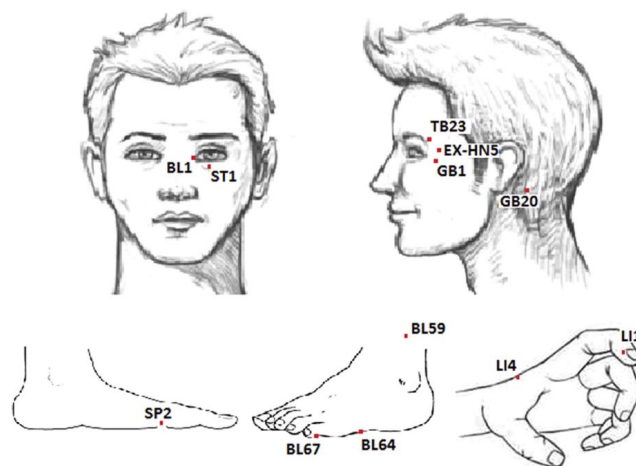


Figure 5: Acupuncture points selected for the amblyopia laser acupuncture protocol.

Our main criteria in producing this protocol, which gave positive results, can be summarized as follows. The periocular points, known as those of the “eye system” due to their function of “nourishing” the eye with the required energy and effective for all eye diseases and visual alterations, were the first choice. From these, we selected the initial points of the yang meridians of the foot (BL1 Jing Ming; GB1 Tong Zi Liao; ST1 Chengqi), and the last point of the Triple Energizer meridian TE23 (Si Zhou Kong), which are the most effective. The most important, in our opinion, is the BL1 (Jing Ming): the point through which the Qi enters the brain. The exit point is the GB20 (Feng chi), which we also

selected. We chose these two points because amblyopia is caused by an incomplete development of the neural tissue involved in the image processing. From the extra-meridian local acupoints, we selected EX-HN5 (Taiyang) in the region of the gallbladder meridian, which stimulates the retinal photoceptors. A second target was the hematic perfusion of the small arteries feeding the retina and the optic nerve, for which we could have included LR3 (Tai Chong) or GB37 (Guang Ming) [55], but we preferred to insert LI4 (Hegu), which in our experience has demonstrated to be effective to quickly normalize the blood flow in the central artery of the retina and in the short ciliary arteries. We added LI1 Shang Yang to support the effect of LI4, and BL59 (FuYang), BL64 (Jing Gu) and BL67 (Chi Yin) based on fMRI evidence [56]. Finally, to stimulate the macula, we selected SP2 (Dadu), the point of

tonification of the spleen, which according to the five elements theory is related to the macula.

Protocol to normalize eye hematic flow in wide angle Glaucoma

In the second case – treatment of hematic eye perfusion in wide angle glaucoma – the protocol we applied is shown in the following Table 3 and Figure 6.

Table 3: Acupuncture points selected for the laser acupuncture protocol for the treatment of the eye hematic perfusion in wide angle glaucoma.		
Acupoint	Name	Position
BL1	Jingming	Just above the inner canthus of the eye
LI1	Shangyang	Just behind the corner of the nail on the radial side of the index finger
LI4	Hegu	In the middle of the 2nd metacarpal bone on the radial side
LI 7	Wenliu	5 cun above the crease of the wrist.
LI20	Yingxiang	In the nasolabial groove, level with the midpoint of the lateral border of the ala nasi
ST1	Chengqi	Below the pupil, between the eyeball and the infraorbital ridge
GB1	Tong Zi Ljiao	Slightly lateral to the outer canthus of the eye in a depression on the lateral side of the orbit
TE23	Sizhukong	In a depression at the lateral end of the eyebrow
EX-HN5	Taiyang	At the temple, in a depression about 1 cun posterior to the midpoint between the lateral end of the eyebrow and the outer canthus of the eye.

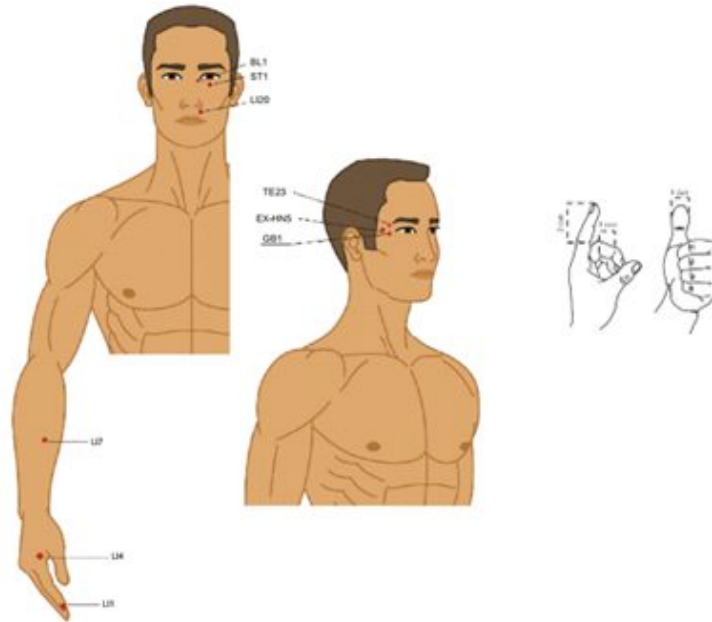


Figure 6: Acupuncture points selected for the laser acupuncture protocol for the treatment of the eye hematic perfusion in wide angle glaucoma.

Our main criteria in producing this protocol, which gave positive results (blood perfusion parameters, ultra-sound resistivity and pulsatility indexes retested at a six-month interval were within the normal range), did not include reducing eye pressure, a choice prompted by the high variability and instability of the therapeutic outcome in glaucoma patients treated with acupuncture. While there are many effective medical and surgical therapies currently available, we decided to focus on normalizing blood perfusion into the eye, a necessary step in all types of glaucoma, particularly when eye pressure is normal, as in normal-tension glaucoma. On the other hand, positive and stable results on the normalization of the blood flow can be obtained in most patients (98 out of 98 patients in our test). We therefore chose to treat the periocular points of the “eye system”, as we did for the amblyopia protocol [BL1 (Jing Ming); GB1 (Tong Zi Liao); ST1 (Cheng qi) and TE23 (Si Zhou Kong)] and LI4 (Hegu) reinforced by LI1 (Shang Yang) and LI7 (Wen Liu). We added LI20 (Ying Xiang), the union point between the large intestine and the first point of the stomach meridians ST1 (ChengQi).

Conclusions

Interest in acupuncture is constantly growing among patients and doctors, thanks in part to rigorous and well-documented systematic reviews which confirm the clinical efficacy of acupuncture treatments for certain specific pathological conditions

(Lu et al., 2022) [57]. Despite this, only a few healthcare systems have incorporated acupuncture into clinical practice guidelines and offer national health coverage for these conditions (Lu et al., 2022) [58]. While decision-making in the health system is an intricate matter requiring consideration of many complex aspects, we believe it would be useful to work in three synergistic directions:

1. Increase the disclosure of data available on evidence-based acupuncture therapies. Comparison of applications and their results requires a clear description of the acupuncture treatment, indicating the stimulated points, type of stimulation [manipulation, electrical (waveform, voltage and current applied), thermal (moxa)], and application time.
2. Research into the mechanisms of action of acupuncture and facilitation of the use of acupuncture therapies in clinical practice to increase the body of evidence and stimulate research. Continuing research into the mechanisms of action underlying the effects of acupuncture point stimulation is crucial, taking all possible sources of stimulation into consideration: not only fixation and manipulation of the needle, but also the modulated electric current, modulated light exposure and mechanical pressure. While there is clear evidence that acupoints are activated by such manipulations, the mechanisms involved are not yet fully understood. Along the same line of the previous paragraph, we would like to

stress that an accurate description of stimulus characteristics is fundamental to ensuring that such research makes a meaningful contribution to the process of understanding and explaining the involved MoAs.

- Promotion of acupuncture therapies in clinical practice. As demonstrated by our experiences with Libralux, the definition of standardized application protocols to be applied by non-TCM-practitioners – besides being beneficial for patients – may also promote a reciprocal understanding between Eastern and Western medicine practitioners. The proposed criterion of the “greatest common factor” among possible acupuncture protocols may be an effective way to achieve this purpose.

Conflicts of Interest

M. Gallamini is the designer of Libralux and a minority shareholder of Fremslife holding the patents rights and producing Libralux. The other authors declare the absence of any conflict of interests.

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