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ACUPUNCTURE IN THE TREATMENT OF PLANTAR HEEL PAIN

A PROSPECTIVE, RANDOMIZED, CONTROLLED STUDY DESIGN

Fernando Jorge Fortunato da Silva Barros

Dissertação de Mestrado em Medicina Tradicional Chinesa

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Dissertação de Candidatura ao grau de Mestre em Medicina Tradicional Chinesa submetida ao Instituto de Ciências Biomédicas Abel Salazar da Universidade do Porto.

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DEDICATION

To my patients,
To my parents,
To my inlaws,

And to my beautiful wife and daughter…

The oppressive pedagogical approach that seeks to embrace the irrational phenomena into a preconceived rational pattern is anathema to me.
In reality things like that answer should remain as they were when they first appear, because only then we know what nature does when left to itself without being disturbed by the presence of man.
You should not use corpses to study life. Furthermore, a repetition of the experience is impossible for the simple reason that the original situation cannot be reconstructed.
Therefore, in each case, there is only one first and single response.

Carl Jung, foreword in "The Book of Changes"

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And last but not least to ICBAS and they leadership. For giving us this unique opportunity, for having the foresight and courage to keep this TCM Master Degree and be first among many, in the service of science and the common good.

RESUMO

Introdução: A dor plantar do calcanhar é uma das patologias musculoesqueléticas mais comuns do pé. Afecta cerca de 10% da população, pelo menos, uma vez ao longo da vida. Terapias comuns, como almofadas do pé, terapia física, AINEs, injeções de cortisona, e ondas de eletrochoque, são consideradas de impacto limitado sobre o prognóstico. O tratamento com acupuntura é uma terapia amplamente aceite para a dor e muito difundida na Ásia, mas apenas dois estudos estão disponíveis em revistas científicas ocidentais, que são inconclusivos e colocam problemas metodológicos, como os critérios subjacentes a seleção de ponto e falta de medidas objetivas, como pela pressão algometrica.

Objetivos:. (1) comparar os efeitos da selecção de acupontos baseada na Medicina Tradicional Chinesa contra efeitos de pontos fora do sistema de condutos conhecido, (2) comparar a acupunção com a acupuntura a laser, de modo a encontrar os melhores parâmetros de estimulação.

Métodos:

Design: estudo prospectivo, randomizado, simples cego e controlado, como já foi aprovado pelos respectivos departamentos do hospital de São Sebastião, e submetido ao Comitê de Ética.

Recrutamento: uma amostra de 60 pacientes, com diagnóstico de dor no calcanhar plantar quando em pé, serão voluntariamente recrutados do Departamento de Ortopedia. Avaliação da elegibilidade ficará ao cargo do Departamento de Anestesiologia, assim como a obtenção de consentimento informado e randomizados em dois grupos de trinta elementos. Dos primeiros trinta elementos, dez serão selecionados para comparar a VA com CA com cinco elementos cada.

Grupos:

O grupo verum acupuntura (VA), será tratado com R7, V66, e L6, através da técnica de mancha de leopardo, o grupo de controlo (CA) será acupuncturado em três pontos situados em áreas de pele pelo menos em 3 cm de distância para os pontos de acupuntura acima mencionados, mas fora do sistema de condutos. O grupo acupuntura Laser (LA) fará tratamento com dispositivo LASERneedle nos mesmos pontos do grupo VA, utilizando um comprimento de onda de 685 nm, a densidade de potência de 4,6 kJ/cm2 por ponto, durante 20 min.

Será comparada algometria de pressão antes e imediatamente após um tratamento único afim de medir os efeitos agudos de tolerância à pressão.

Em um segundo ensaio, os pontos do grupo com o melhor resultado serão tratados por agulhamento convencional vs acupuntura laser para saber mais sobre os parâmetros ótimos de estimulação duas vezes por semana durante três semanas.

Os principais parâmetros serão medidos antes e depois de cada tratamento e incluem: escala visual analógica, algometria pressão (usando plataforma validada) e uma balança convencional. Após a conclusão do tratamento todos os pacientes serão convocados depois de 3 semanas para acompanhamento e medições.

Resultados: Diferenças significativas entre o grupo VA e CA são esperadas. Nós supomos pela experiência prática, que o tratamento com os melhores efeitos agudos provavelmente também será melhor em tratamento crônico. Comparação entre VA e LA pode revelar mais algumas informações sobre o tipo ideal de estimulação.

Conclusões: O estudo foi concebido para revelar dados básicos para um estudo prospectivo, randomizado, duplo-cego, no futuro, com ótimos parâmetros de estimulação e seleção de ponto, e medições objetivas por algometria de pressão, além de VAS.

Palavras chave: Dor plantar do calcanhar, acupunctura, laser, pressão plantar, algometria, Medicina Tradicional Chinesa

ABSTRACT

Introduction: Plantar heel pain (PHP) is one of the most common musculoskeletal pathologies of the foot. It affects about 10% of the population at least once throughout their lives. Common therapies, like foot pads, physical therapy, NSAID's, cortisone injections, and electroshock waves, are regarded as with limited impact on prognosis. Acupuncture treatment is a widely accepted therapy for pain. Acupuncture in PHP is widespread in Asia but only two studies are available in peer reviewed Western journals, which are inconclusive and enclose methodological problems such as criteria underlying point selection and lack of objective measurements, such as by pressure-algometry.

Objectives:. (1) to compare effects of TCM-based acupoint selection versus effects of points out of the known conduit system; (2) to compare needling with laser acupuncture so as to find the optimal stimulation parameters.

Methods:

Design: prospective, randomized, single blinded and controlled study, as already approved by the respective departments of the hospital St Sebastian, and submitted to the Ethical Committee.

Recruitment: A sample of 60 patients, with diagnosis of plantar heel pain when standing, will be voluntarily recruited from the Department of Orthopedics. Eligibility evaluation in the Anesthesiology Department, obtainment of informed consent and are randomized in to two thirty elements groups. From the first thirty, ten will be selected to compare VA to CA with five elements each.

Intervention: The **verum acupuncture group (VA)** will be treated with R7, V66, and L6, by the leopard spot technique; **the control group (CA)** will be acupunctured on three points in skin areas located at least in 3 cm distance to the above mentioned acupoints, but out of the conduit system. **Laser acupuncture group (LA)** with LaserNeedle device and treatment of the same

VA group points using a wavelength of 685 nm, power density of 4.6 kJ/cm2 per point, during 20 min.

Pressure algometry will be compared before and directly after one single needling treatment to measure acute effects by pressure tolerance between VA and CA group.
In a second trial, the points of the group with the best result will be treated by conventional needling vs Laser acupuncture to find out about the optimal stimulation parameters twice a week over three weeks.
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Main parameters will be measured before and after each treatment and include: visual analogue scale, pressure algometry (using validated pedography platform) and a simple regular scale. After treatment completion all subjects will be recalled after 3 weeks for follow-up measurements.

Results: Significant differences between the VA and CA group are expected. We hypothesize by practical experience, that the treatment with the best acute effects will probably also be better working in chronic treatment. Comparison between VA and LA may reveal some more information about the optimal type of stimulation.

Conclusions: The study is designed to reveal basic data for a prospective randomized double-blinded study in the future with optimal stimulation parameters and point selection, and objective measurements by pressure algometry in addition to VAS.

Keywords: Plantar heel pain, acupuncture, laser, plantar pressure algometry, Traditional Chinese Medicine

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LIST OF ABBREVIATIONS

PHP – plantar heel pain

NSAID – non steroid anti inflammatory drug

TCM – Traditional Chinese Medicine

N - Newton

Kg - kilograms

VAS – visual analogue scale

VIP – vasointestinal peptide

NGF – nerve growth factor

VGF – vascular growth factor

RCT – randomized controlled trials

ALT – Algor Leadens theory

ASA – American Society of Anesthesiology (physical status classification system)

VA – verum acupuncture

LA – laser acupuncture

SA – sham acupuncture

LLLT – low light laser therapy

PGE2 – prostaglandin E2

mRNA – messenger ribonucleic acid

COX 2 - Prostaglandin-endoperoxide synthase 2

IL-1β – interleukin 1 β

TNFα - tumor necrosis factor-alpha

1 – INTRODUCTION

According Cotchett et al. (2010) plantar heel pain is one of the most common musculoskeletal pathologies of the foot. The same author states that this disease affects about 10% of the population at least once throughout their lives, while stating that there are very few epidemiological studies of quality in this field. Common therapies, like foot pads, physical therapy, NSAID's, cortisone injections, and electroshock waves still have insufficient prognosis.

A literary survey was conducted using electronic databases including PubMed, B-on and Science Direct, as well as several books concerning the matter.

This showed that are few published studies about the use of acupuncture for heel pain and none of them had a objective quantitative method of measurement and used exclusively a visual analogue scale and foot or otherwise health related surveys, are unclear to the underlying criteria of point selection, used poor controls and lack objective measurements used in the study of foot conditions like pressure algometry.

The objective of this thesis is to propose a study protocol that covers more adequately the question of the specific effects of acupoints and different type of stimulation in plantar heel pain.

In the first part of this work a theoretical background is presented with the common medical approach to plantar heel pain, modern considerations on acupuncture effects and recent findings, the bases of the Heidelberg Model of TCM, and TCM approach on PHP, laying the theoretical foundation and justification for the choices that were made on the proposed design described in the second part of this master thesis.

The study has already been submitted in the Centro Hospitalar de Entre Douro e Vouga, was approved by the Head of the Anesthesiology Service, Head of the Orthopedics Service, and the Coordinator of the Pain Unit, and pre-recruitment measures have been taken at the timepoint of this master thesis deadline.

Being so the last part of this presentation only address expected results and the conclusions await for preliminary results, reflect on current limitations, and propose further studies.

2 – BACKGROUND

2.1 - CHARACTERIZATION OF PLANTAR HEEL PAIN

2.1.1 – EPIDEMIOLOGY

The Clinical Practice Guideline on Heel Pain Panel of the American College of Foot and Ankle Surgeons states that mechanical factors are the most common etiology of heel pain. Other causes include traumatic, neurologic, arthritic, infectious, neoplastic, autoimmune, and other systemic conditions.

According Cotchett et al. (2010) plantar heel pain (PHP) is one of the most common musculoskeletal pathologies of the foot. The same author states that this disease affects about 10% of the population at least once throughout their lives. PHP is more common in middle-aged obese females and young male athletes (Juliano, 2004) The incidence is higher in the athletic population but not all suffering present for medical treatment.

A number of risk factors have been proposed but there is little evidence to back up some of these claims. The risk factors reported in the literature and have included overuse, over-training, excessive body weight, and biomechanical changes to the properties of the soft tissue and/or altered biomechanics in particular excessive foot pronation. Occupations that require extended periods of weight-bearing have also been reported with the development of PHP. There seems to be a general agreement that obesity or increased body mass index and increased pronation are definite risk factors for PHP, with age and reduced metatarsophalangeal joint extension. (Irving, 2006)

The association between PHP and heel spurs remains a subject of controversy. A number of papers have reported a positive association between heel spur and PHP. However, most of these are retrospective case series and as such do not indicate causation. Heel spur is actually fairly common in the general population and the presence or absence of a spur has not been found to correlate with the patients' symptoms. Thomas (2001) and Irving (2006).

2.1.2 - DIAGNOSIS AND CONVENTIONAL TREATMENTS

Acording to the book Harrison's Internal Medicine the diagnosis of PHP can usually be made on the basis of history and physical examination alone. The onset of PHP is gradual, or immediate on weight bearing. Patients experience severe pain with the first steps on arising in the morning or following inactivity during the day. The pain usually lessens with weight-bearing activity during the day, only to worsen with continued activity. Pain is made worse on walking barefoot or up stairs.

For the differential diagnosis of PHP the following diagrams included in the Clinical Practice Guideline on Heel Pain Panel of the American College of Foot and Ankle Surgeons show very clearly how this is made by pathways of differentiation and include the most common conventional treatments for PHP:

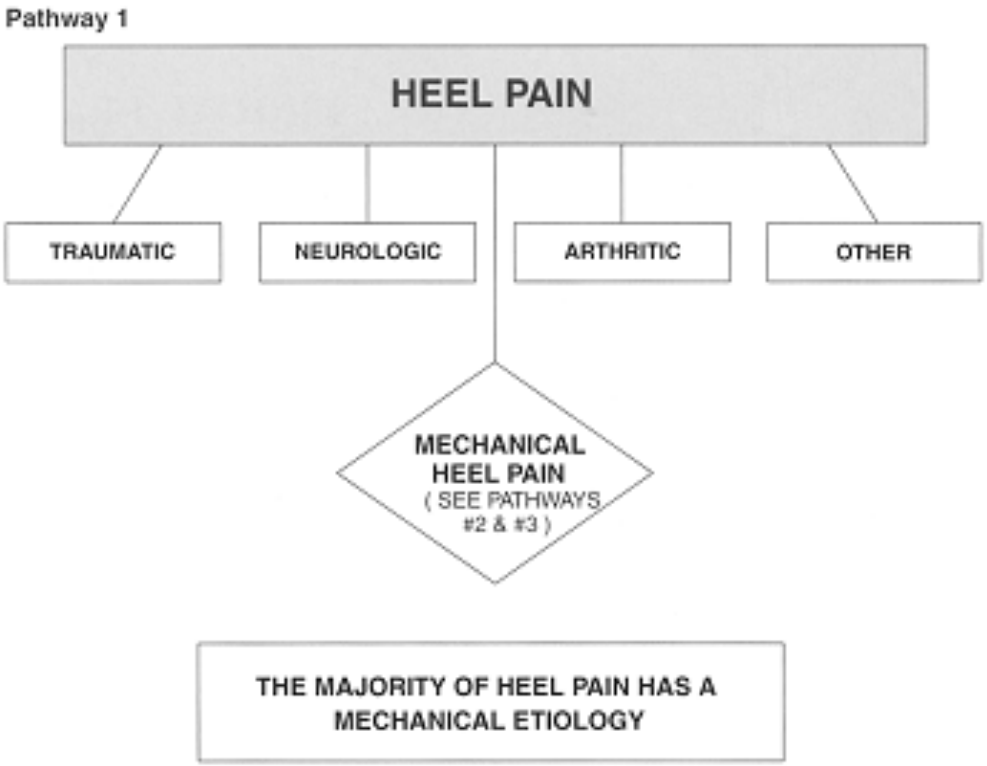


Figure 1- Pathway one of diagnostic differentiation in heel pain. In *Clinical Practice Guideline on Heel Pain Panel of the American College of Foot and Ankle Surgeons* (2001)

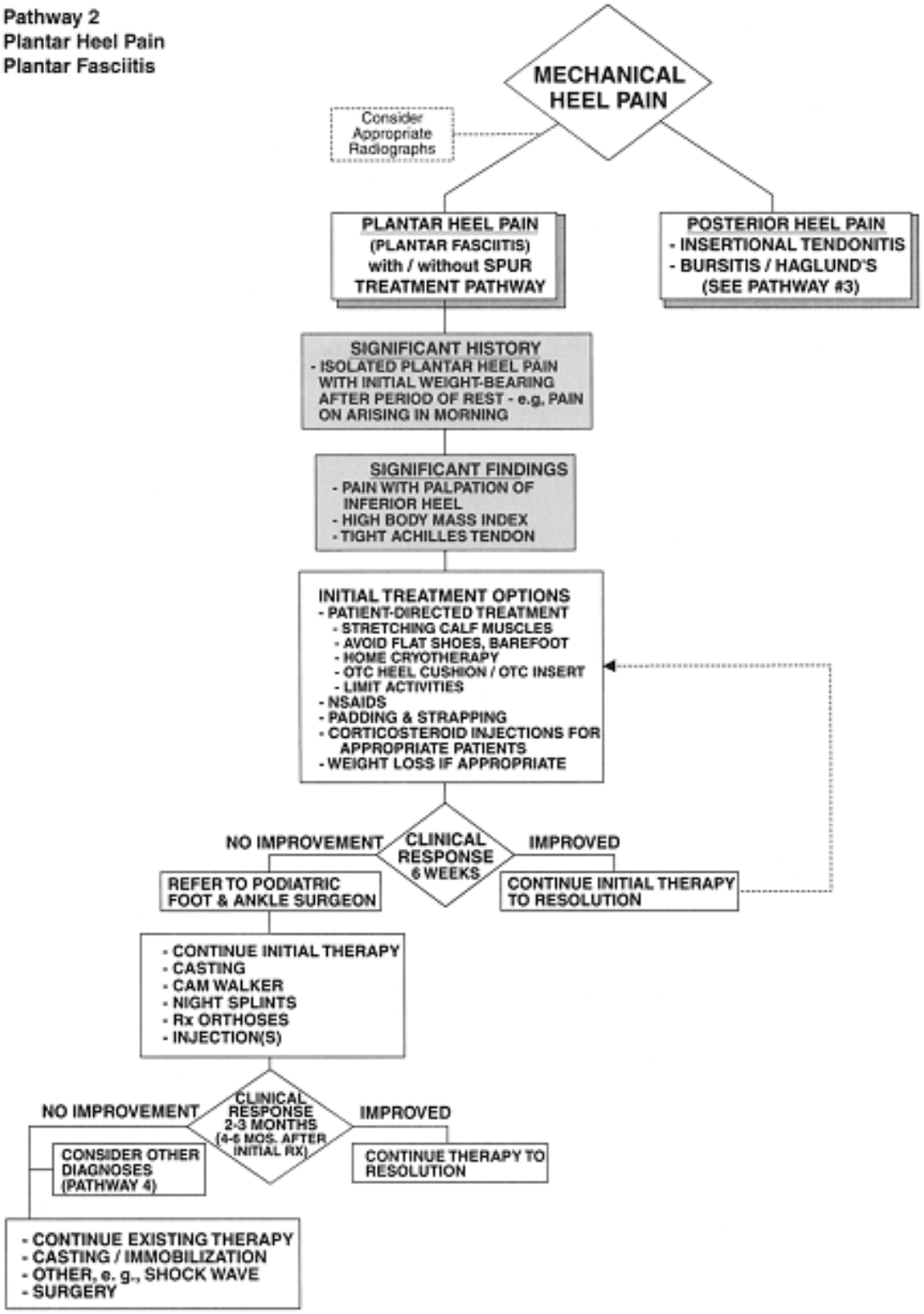


Figure 2 - Pathway two of diagnostic differentiation in heel pain and corresponding clinical approaches. In *Clinical Practice Guideline on Heel Pain Panel of the American College of Foot and Ankle Surgeons* (2001)

2.2 - PRESSURE ALGOMETRY IN THE ANALYSES OF THE FOOT

Recent technological advances have given researchers more reliable and precise instruments to evaluate the biomechanics of the foot.
These instruments are baropodometric platforms and insoles with hundreds of sensors that can measure independently infracentrimetical areas of the plantar area giving a very precise realtime picture of plantar pressure distribution.

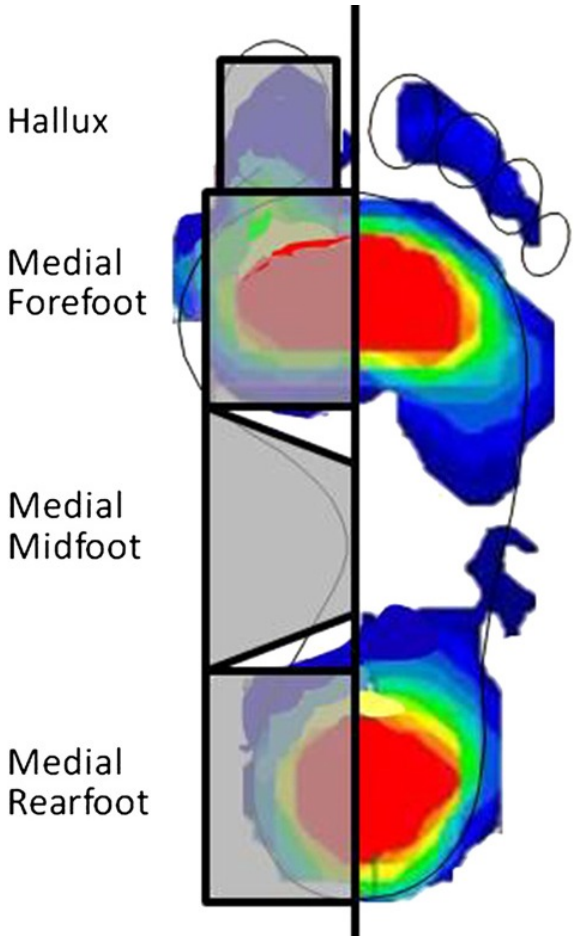


Figure 3 – In *Relationships between clinical measures of static foot posture and plantar pressure during static standing and walking*. Jonely et al. (2011)

They show measurements in N/cm2. The SI unit Newton is equal to the amount of net force required to accelerate a mass of one kilogram at a rate of one meter per second squared. It is the unit of Force and it relates to the Second Law of Newton. So if we want to compare N with kg's we can say that on Earth's surface, a mass of 1 kg exerts a force of approximately 9,8 N.

So measurements can be of total force (N), total contact surface (cm2) and maximum peak pressure per area (N/cm2).
Then for the analyses of plantar pressure distribution several methods are used for dividing the plantar areas with bigger or smaller areas according to specific designs or evaluation necessities.

These measurement instruments (insole and platform) are expensive and difficult to find and have some differences in measurements as shown in a study by Chevalier et al. (2009). The main reason for this is individual footwear design that causes different areas of contact and naturally a discrepancy of maximum peak pressures. This can be solved by the use of the same footwear as found in a study on the effects of plantar fasciitis and pain on plantar pressure distribution in recreational runners by Ribeiro et all. (2010).

All these facts decrease the feasibility of studies particularly on a non athletic population. In this study we will also try to approach this problem and propose to use a simple scale to measure total force (N) expressed in Kg, in order to solve the problem of availability of measuring instruments.

For this study a emed® pedography platform by Novel Germany was available. The present design proposes to evaluate plantar peak pressure and distribution diferences on weight bearing before and after acupuncture treatments and compare it to pain scores (VAS) in order to objectively measure outcomes.

During my literary survey, I have found six studies that evaluate plantar pressures using insole systems (Jonely, 2011; Chevalier, 2008; Teh, 2005; Hodge 1999; Bonnanno, 2010; and Ribeiro, 2010), five during walking or running (Chevalier, 2008; Teh, 2005; Hodge 1999; Bonnanno, 2010; and Ribeiro, 2010) and only one on static standing (Jonely, 2011) and one using a platform but during walking (Chevalier, 2008).

Only one study that was found that evaluated static standing of PHP patients. In it his author Alves et al. (2008) suggest that some foot postures may be protective against some types of injuries and describes what specific changes

of foot postures can be found. The author states that the patients affected tend to shift their pressure distribution towards the fore and lateral aspects of the foot making the answer to the question of what parameters, and phenomena should be then analyzed easier to answer.

After reading all studies the division of plantar areas used point to the division of medial and lateral foot, fore, mid and rear foot, hallux and the other four fingers as the maximal common denominators making a total of 8 different areas.
The parameters will then be: total plantar force (N), total plantar area (cm2), and peak pressure value (N/cm2) and peak pressure percentage (%) for each area for a total of 18 parameters and should be sufficient for a full evaluation of foot posture and pressure distribution changes.

2.3 - LOW LEVEL LASER THERAPY

Low level laser therapy (LLLT) has been available for nearly three decades, and scattered positive results have been countered by numerous negative trial results. Bjordal et all. (2006)

A systematic review made by Bjordal et all. (2006) suggests that there is strong evidence from 19 out of 22 controlled laboratory studies reviewed that Low level laser therapy (LLLT) can modulate inflammatory pain by reducing levels of biochemical markers (PGE_2, mRNA Cox 2, IL-1β, TNFα), neutrophil cell influx, oxidative stress, and formation of edema and hemorrhage in a dose dependent manner and concluded that LLLT can be used to significantly reduce acute inflammatory pain in clinical settings.

In a randomized, double-blind, placebo-controlled study of low-level laser therapy (LLLT) in 90 subjects with chronic neck pain was conducted by Chow (2006) in order to determine the efficacy of 300mW, 830nm laser in the management of chronic neck pain. Results showed statistically significant results in the verum group showing thus the efficacy of LLLT in chronic neck pain.

This shows that the effects of LLLT are mainly dependent on laser wave length and dose ranges.

In a compilation of studies conducted by Litscher et al.(2001) using a LaserNeedle device like the one available for this study, the author shows that its application on acupuncture points using a wavelength. of 685 nm, power density of 4.6 kJ/cm2 per point for a duration of 20 minutes elicits specific effects on microcirculation of the skin by augmenting it,and on the blood flow velocity in the ophthalmic artery, using TCM based point selection.

Using a fMRI as measurement tool significant changes in brain activity were registered in the occipital and frontal regions during stimulation of distant, visual acupuncture points and near the olfactory cortex during the activation of

acupuncture points, which, according to TCM, have a connection to the sense of smell. Further, significant activation occurred after stimulating the Yintang point in the front-parieto-temporal region, with massive electroencephalographic alterations (appearance of frontal delta activity). Litscher et al.(2001)

As these interventions showed to be beneficial and safe the stimulation parameters used were suggested for this study's laser intervention.

2.4 - NEUROPHYSIOLOGICAL BASIS OF ACUPUNCTURE AND LATEST ACUPUNCTURE RESEARCH

The physiological response of Acupuncture is defined as a stimulation technique of the various mechanisms of self-regulation of our body through the nervous, endocrine and immune systems (Ferreira, 2010).
This regulation of the nervous system and its effectors is achieved by action at 4 levels: local, segmental or spinal, extra segmental, and supra-segmental or supra spinal (Ferreira, 2010).

– Local: acupuncture stimulates peripheral neurological sensory receptors, in particular the free nerve endings, consisting predominantly of the delta fibers, skin, and muscle fiber type II and III which are interconnected forming a net charge of propagation of the nervous stimulus to blood vessels and local immune cells (Ferreira, 2010).
These peripheral receptors propagate the stimulus to local network of neurons and produce what is called "axonal reflex." According to Ferreira (2010), the reflection that occurs without the need for a center cord integration, will induce an increase in local blood supply due to release of various vasoactive substances such as substance P, bradykinin, related polypeptide gene colcitonin, VIP (vasoactive intestinal peptide), Histamine, Serotonin, NGF (nerve growth factor), VGF (vascular growth factor) etc.
In addition to the local effects as described, there is still the release of biochemical analgesic substances as the β endorphin in large amounts, which potentiate the analgesia locally by acting on the peripheral sensory receptors and blocking nociception (Ferreira, 2010). These substances are released by local inflammatory cells (granulocytes), demonstrating a sort of activation of the immune system by acupuncture.

– Segmental or spinal: the gate theory of Melzack and Wall is fundamental to understanding the so called segmental effect of acupuncture. According to the authors of this theory, a myelinated nerve fiber and high-speed driving (e.g., aδ or aβ) if stimulated in a damaged area, carries its information to the CNS faster than a myelinated fiber with low speed that is stimulated by local pain. On

reaching the posterior horn of the spinal cord, these myelinated fibers cause a blockage of nerve impulse transmission originating from the C fibers (slower) (Melzack and Well cited by Ferreira, 2010) by enkephalins and release of GABA inhibitory neurotransmitters, released by interneurons at the level of the posterior horns of the spinal cord.
The various tissues of our body, even though sometimes very far apart, can have the same innervation as during embryonic development originated in the same segment, allowing us to understand that, to give effect to the level of a particular nerve root, we can put the needles in structures with the same innervation of the affected site, exerting an effect on posterior horns of the spinal cord at the level of the spinal segment stimulated (Ferreira, 2010).

– Extra-segmental: this mechanism of analgesia is nonspecific or generalized, depending on the intensity of the stimulus and not its location. It acts by controlling the periaqueductal gray matter in the brain stem, spreading through the descendant inhibitory beams to the posterior horn of the spinal cord, depressing the activity of nerve cells located here.

– Supra-segmental: this mechanism of action is located at the level of the cerebral cortex and spreads to the spinal spinal by descending inhibitory beams. After the thalamus and the reticular system process the information received by the impulse of the puncture, it is driven to various areas of the cerebral cortex, including the centers of information processing as a primary sensory cortex or somatosensory, the cerebellum, the limbic system, the prefrontal cortex, among others, each of which, in turn, will respond to these stimuli in its own way (Ferreira, 2010). The use of electrostimulation allows potentiate the effect of supra-segmental acupuncture.

The above explanation of acupuncture effects reflects the common understanding of the medical community on the so called modern or medical acupuncture therapy.
It does not reflect on the specific effects of acupoint stimulation as suggested by TCM. These conclusions also report to the treatment of pain and until recently it

remained unclear whether the positive effects of acupuncture are specific to acupoints or to all kinds of puncture as suggested by Linde (2009).

Curiously same author on a recently published study that consisted in a systematic review to identify randomized controlled trials of acupuncture for chronic pain in which allocation concealment was determined unambiguously to be adequate and individual patient data meta-analyses were conducted using data from 29 of 31 eligible RCTs, with a total of 17922 patients analyzed states in his conclusions that acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture. Linde (2012)

These findings pave the way and justify for TCM based acupuncture research in the future has a way to understand those factors that are beyond simple needling. In most studies a TCM based acupoint selection is left out of the equation. So there are still doubts if TCM based acupuncture clinical benefits are caused by non specific physiological effects of needling or the specific acupoint selection.

In response two double-blinded placebo controlled trials were published by Hauer et al. (2011) on gait performance in geriatric patients, and Sertel et al. (2009) on nasal congestion, that used TCM based acupuncture, and TCM individual diagnosis based acupuncture as point specific effect (verum) acupuncture versus a technically identical needle application on a nonacupoint out of the known conduit system as control.
Both studies showed significant statistical improvement on studied parameters by comparison.
In TCM there are innumerous types of interventions for stimulating acupuncture points. From rotating, thrusting, pricking, heating, burning, cupping, pushing, rubbing, bleeding etc. These specific forms of manipulation of the acupuncture point and the various responses obtained, since, ultimately, each form of stimulus generated by manipulation of the needle or otherwise can release

specific neurotransmitters that may inhibit or excite the synapses in the nervous system in multiple ways and, with this, also promote specific responses (Yamamura, 1993)

As there are still many questions about these subjects, the present research project intends to approach these two questions by using a TCM based specific point selection versus a nonspecific point selection and two types of specific point stimulation.

2.5 - THE HEIDELBERG MODEL OF TCM

The Heidelberg Model of TCM is based on a system of sensations and discoveries to establish a functional vegetative state or to describe functional abnormalities through its signs and symptoms resulting from disorders of the body tissues (Porkert, 1983; Greten, 2008). This condition can be treated by use of Acupuncture, Moxa, TuiNa, Pharmacotherapy, Dietetics, Psychotherapy, TaiChi, and Qigong.

According to the Chinese medical thinking, the individual is rated holistically, so detect phenomenon are precursors of organic and functional changes that cause the appearance of symptoms and signs. Thus, all information and relevant characteristics of the patient are brought together to form a "pattern of disharmony", the resulting imbalance process, caused by the environment, external source, or by the size of emotional retained efforts, of internal origin which describe the functional state of the patient and consequently provide the framework for the treatment.

According to the Chinese medical perspective, the mind and body are not viewed as a mechanism complex, but as a circle of energy and vital substances interacting with each other to form the body.

QI

One of the fundamental concepts of TCM's "Qi", usually translated as energy, life force or vital energy is the basis of everything an immaterial form that promotes dynamism, the activity of the living being.

According to the model Heidelberg, "Qi" is understood as the capacity for vegetative function of tissues or organs that can cause the sensation of pressure, tear or flow.

According to Porkert (1983), Qi is defined as the immaterial energy with a qualification and direction.

In Chinese medicine, the "Qi" has two main aspects. On one hand, designates the essence (Jing), which have the function of constructing the body and the mind (Shen). On the other hand, indicates the complex functional activities to maintain both.

If the "Qi" flourishes, there's health; if it is weak, there is pathology, whether it is balanced, there is tranquility, If not move in the wrong direction, no pathology. Therefore, processing and correcting the direction of movement of "Qi" is the basis for the motion of Xue (Blood) transformation of essence (Jing), movement of body fluids, food digestion, nutrient absorption, excretion, wetting the tendons and bones, hydrating the skin and increase resistance to external pathogenic factors.

SHEN

Another concept that is also critical is the shen. Shen is comparable to the ability to carry out certain higher brain functions in Western medicine. According to Porkert (1995) shen is the force that originates from the constellation of the orb of the heart and is another expression of extremely specialized "Qi". Greten (2008), defines shen as the functional capacity to put in order mental associativity and emotions, creating thus the presence of mind. The functional status of shen is assessed by signals such as coherence of speech, the "sparkle" in the eyes and fluid fine motorics.

XUE

The Xue despite having a different concept of blood in Western medicine is the functional capacity (energy) linked to body fluids, functions of warming, moisturizing, create "Qi" and nourishing the tissues (Porkert, 2001) it is driven by the "Qi" in the system of channels - conduits. From the standpoint of the Western medical sciences, the clinical effects of Xue can be compared to the effects of microcirculation, including functional relationships, blood cells, plasma factors, endothelium and parenchyma (Greten, 2008).

The Xue despite having a different concept of that of blood in Western medicine is the functional capacity (energy) linked to body fluids, with the functions of warming, moisturizing, creating "Qi" and nourishing the tissues (Porkert, 2001) and it is driven by the "Qi" in the system of channels - conduits. From the standpoint of the Western medical sciences, the clinical effects of Xue can be compared to the effects of microcirculation, including functional relationships, blood cells, plasma factors, endothelium and parenchyma (Greten, 2008).

Xue has a dual nature: it is part of the yin and substance, and at the same time is a form of yang energy. This dual nature of xue becomes obvious in functional relation of Xue Shen and since the xue (yin) "checks" / or "controls" the shen (Yang) (Greten, 2008).

YIN and YANG

The concepts of Yin / Yang and the base are probably the most distinctive and important of the whole theory of Chinese medicine, and are used to explain the organizational structure of the human body, their physiological functions, and laws relating to the causes and evolution of diseases.

They are not absolute terms but comparative ones. One thing can be rather yang then yin or vise versa but not absolutely.

Thus, under this view, Yin and Yang are manifestations of a duality, an alternation of two opposite stages in time. Every phenomenon in the universe is changed by a cyclic movement of ups and downs, and the alternation of Yin and Yang is the driving force of this change and development, ie each phenomenon may belong to yin or yang, but always contains the seed opposite the stage itself. The day turns into night, summer into winter, deterioration in growth and vice versa. Thus, the development of all phenomena in the universe is the result of an interaction of two opposing stages, symbolized by Yin and Yang, and each phenomenon itself contains both aspects in varying degrees of expression. The day belongs to Yang, but after reaching its peak at noon, the Yin within it gradually begins to unfold and manifest (Porkert, 1995).

So in Chinese medicine is pertinent to understand the yang as an active aspect, an activity / function, while the yin has a constructive and structural character.

All body structures, organs and phenomena contain a predominant character yin or yang, fundamental for the balance of the human body. The two forces regulating yin and yang must be in a dynamic equilibrium that maintains normal physiological activities of the organic system. If this balance is affected by factors of illness, with predominance or lack of one of the two parties, pathological processes are manifested.

The Heidelberg Model of TCM, based on a simple concept of a self regulated cybernetic system confronts the yin and yang, explaining the circle of the

classical binomial through circular functions in a manner resembling a simple sinus curve.

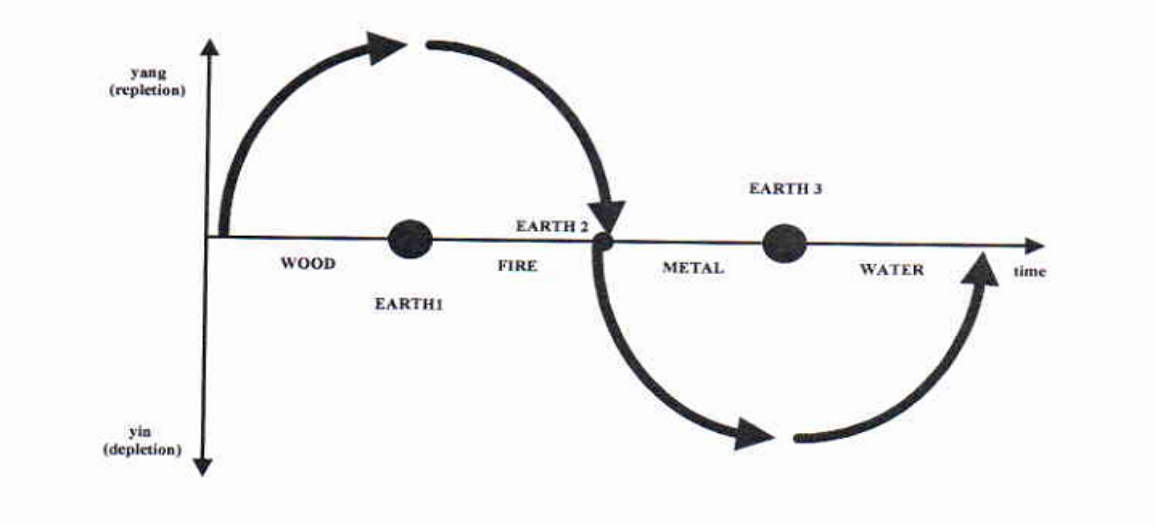


Figure 4 – Phases in a sinus wave. In *Understanding TCM* Greten (2008)

This symbol is a good description of yin and yang, the five phases and their linkages: the center (Earth) as a vector that contributes to the equilibrium exercises a down-regulation in the 1st half of the movement and an upward adjustment in second half. Yang or repletion / excess is represented by an increased activity above the center. The yin or depletion / deficit is reflected by an activity below the target value. According to Greten (2008), we talk about yin or yang depending on whether it is above or below the "target value" respectively.

PHASES and ORBS

In TCM the five evolutionary phases designate vectors that are representative of five qualities of natural phenomenon, five movements, five stages (Wood, Fire, Earth, Metal and Water) and relate to the movement of "Qi" (Greten, 2008), used to classify all phenomena, areas, sounds, smells, tastes and all the familiar things in the universe, there is a link between the five evolutionary phases (vegetative trend) and orbs (organs), the anatomical regions and emotions.

According to the scientific approach of the Heidelberg Model for Chinese Medicine, one phase is that part of a circular process, which when applied to humans, shows the trends of the individual functional vegetative state at that particular time. These manifestations are called orb (Greten, 2008). Each stage corresponds to one vector and a distribution of "Qi" which leads to specific signals that could be relevant to the diagnosis (orbs).

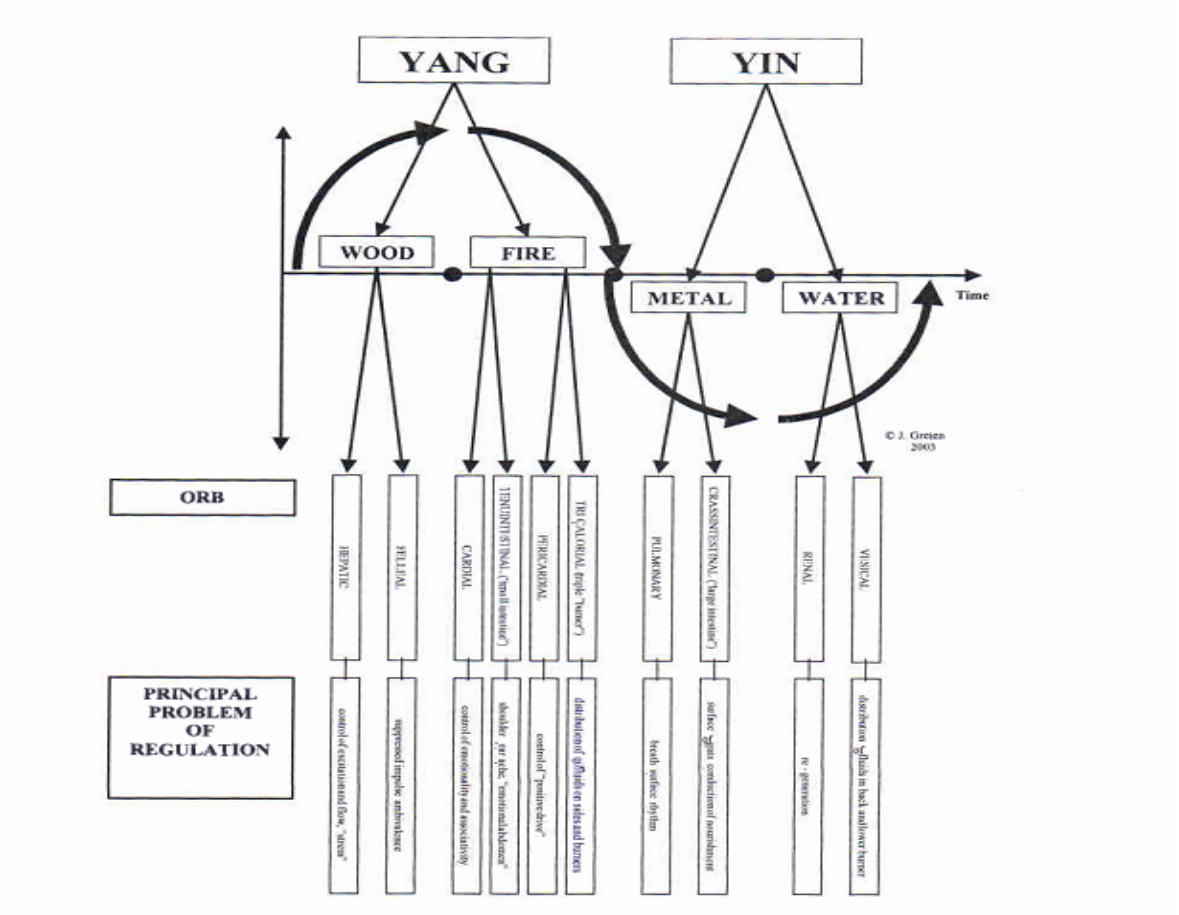


Figure 5 – Diagnostic pathways. In *Understanding TCM* Greten (2008)

The phases consist of a cyclic ordering that can be registed as a sinusoidal wave around a target value (axis). Each phase is represented by two orbs, one with yin characteristics and the other with yang characteristics, with the exception of the phase Fire having four orbs. This sinus wave analyzes the problems of transition from one phase to another. This circular function is called cybernetics and explains how the yin and yang and the circular functions are important to medicine, with regard to the model of regulation (Greten, 2008).

The sinusoidal curve describes eight transitions, Wood - Earth - Fire - Earth - Metal - Earth - Water - Earth (Greten, 2008).

It is a very useful tool in the analysis of problems of transition from one phase to another. The model of the six stages, aka Algor Laedens Theory (ALT) uses a sinusoidal curve in order to characterize the action of the orthopathy (the "straight path" or the healing power of the body). In Western terms this is the action of the immune system. Thus, in accordance with the laws that describe regulatory processes (cybernetics), the episodes of periodic fluctuations that exist around a target value, activating and deactivating the systems and mechanisms of transition are responsible for the bodily changes that will manifest in different functional vegetative states of body and that come with, and are shown through the sinusoidal curve.

The more we move away from the target value regarded as normal, the more mechanisms of self regulation are active. This is symbolized by the vectors leading the effective value to normal. If we project these ortopathic force vectors we get a reverse sinusoidal curve.

According to the western medical sense, the graph shown may be representative of the global vegetative activity, including central nervous system via the transmitter and vegetative systems involved.

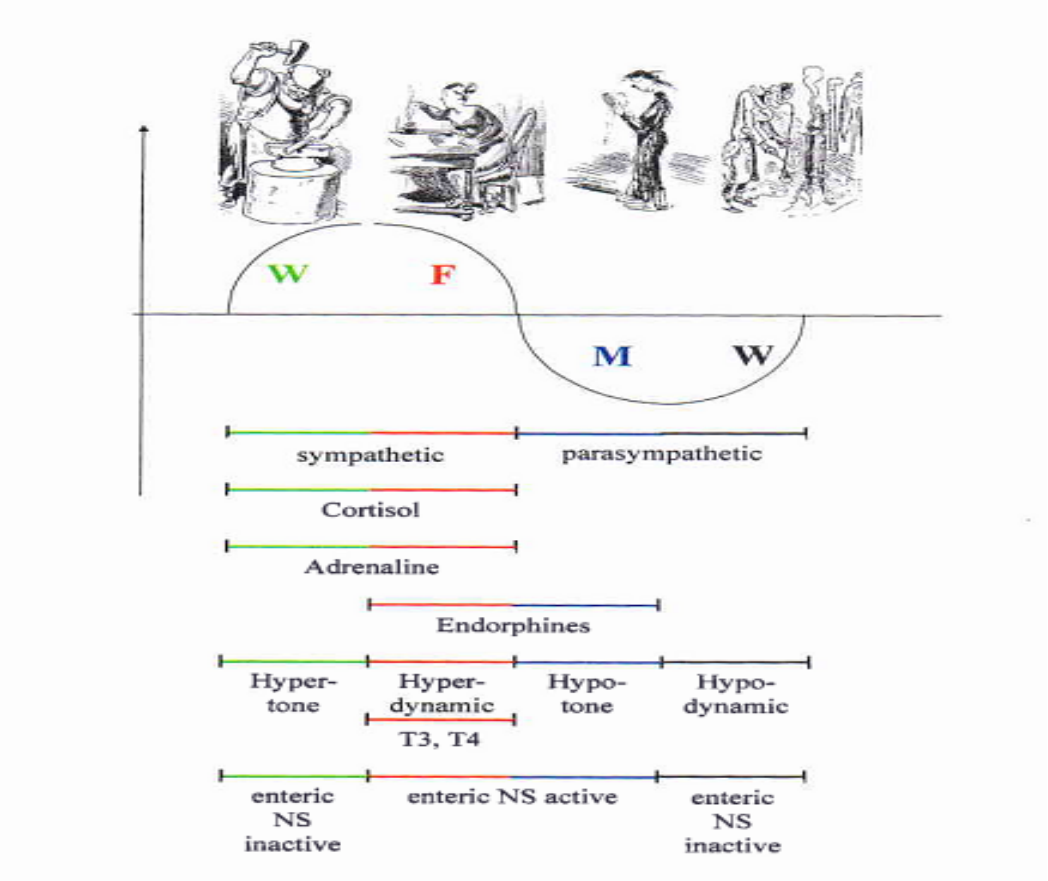


Figure 6–Vegetative system and phases. In *Understanding TCM*, Greten (2008)

The phases yang (Wood and Fire) are mainly regulated by the sympathetic nervous system functions, whereas the phases yin (Metal and Water) dominates the activity of the parasympathetic nervous system (Greten, 2008). In TCM the system of correspondences is interpreted as follows:

– The phase Wood has the potential creator, is associated with growth functions, upward movement, surveillance, potential energy, symbolizes the East and Spring, and is manifested in the Hepatic (Liver) and Felleal (Gallbladder) orbs. The hepatic orb maintains and produces all the decision making and planning, is the source of courage and presence of mind, it is considered the replenisher of the Qi Constructivum - specific of xue. The Felleal orb controls and guides the initiative and the decision, controls all forms of Qi, for example, controls the flow of Qi Constructivum through the conduits, causing the movement of Qi Defensivum to ascend out of them (Porkert 1987).

– The phase Fire has the potential for the transformation into function, represents the functions that reached their maximum stage and are about to start their decline, symbolizes the South and Summer, and corresponds to the Cardinal (Heart) Tenuintestinal (Small Intestine), Tricaloric (Triple Burner) and Pericardic (Pericardium) orbs.

The Cardiac orb directs and influences all the others, so it is considered the "Emperor" that governs the conduit system, the transformation of Qi Constructivum into xue, being primarily responsible for the movement of it, also for fine motorics, coherence of speech, bodily and mental functions, integration of all functions and vital processes, including metabolism. An important aspect of this force coordinator is sleep physiology, when the forces are removed, Shen the active structure of the heart. As a rule, the aspects of metabolism, regulation of juices and nutrition are taken by Tenuintestinal orb.

The function of Pericardial orb is compared to an "official ambassador," it is the source of joy and pleasure. It is defined as a reservoir of Qi attributed to the individual at birth. Some theories say that has an affinity in the development of infectious diseases. It tends to suffer first with the external factors while the Cardiac orb is most affected by endogenous agents, emotions and constitutional disorders (Porkert, 1983). The Tricaloric orb is a complement of the Pericardial orb and dependent of the Tenintestial orb. It is responsible for regulating the movement of fluids.

– The phase Metal has a relative lack of energy, is responsible for the rhythmic distribution of energies, symbolizes the functions that are in decline, represents the West and autumn, is associated with the Pulmonary (lung) and the Crass Intestinal orbs (large intestine).

The pace of the individual - the result of the synthesis between the congenital Qi, stimuli and influences of nature, society and the cosmos (food, weather, moods, intellectual stimulation) is produced in the pulmonary orb. The Defensive Qi is in the skin and this is the perfection of pulmonary orb. Its physiological function is the downward movement and distribution of energy captured by respiration to the middle and lower caloric (Porket, 1995). The CrassIntestinal orb, is a forwarding agent, it transports and contributes to food processing already initiated by the Stomachal and TenueIntestinal orbs.

– The phase Water represents those functions that have reached the maximum state of decline, and are ready to move in the direction of growth and regeneration of energies, it symbolizes North and Winter, the downward movement of moistening is associated with the Renal (Kidney) and Vesical (Bladder) orbs.

The orb Renal is the place of "congenital constitution", where all the inherited potential and hereditary traits reflects, and represents all neurological functions (intellectual, mental potentiation of sensory impressions in the form of knowledge), all the "neuronal output." The Vesical orb is a complement of the Renal orb, functioning as a fluid buffer, as materialization of inherited resources and reserves for future demonstrations. Its function is the elimination of the excess fluid (Porket, 1995)

– The phase Earth represents the idea of regulation, balance, the Centre, symbolizes the late summer, allows the spreading, growth and harvest. The Stomachal (Stomach) and Lienal (Spleen Pancreas) orbs represent these functions.

The Stomachal and Lienal orbs are defined as spheres of integration and assimilation of external effects, and are responsible for integration, incorporation and assimilation of all the action potentials and forces affecting the individual from the outside to the inside. This power of assimilation and digestion corresponds to the life force that is reborn every day. Therefore, the orbis Lienalis is called the origin of the acquired constitution (postnatal) and is also considered the center of constructive energy. The Stomachal and Lienal orbs are important in the metabolism of food and drink, as well as its distribution. It is the splenic orb that the constructive Qi is located, providing the conditions for producing Xue. The energy active lienal maintains xue intact, firmly ensures the blood vessel and prevents bleeding. These orbs are important in the digestion of sensations and mental work performance (cogitation), revealing also to be important to harmonize and balance all other orbs (Porkert, 1995).

2.5.1 - TCM DIAGNOSTICS ACCORDING TO THE HEIDELBERG MODEL

Diagnosis in TCM should become more standardized, rational and communicable as it from it that largely depends the direction of the interventions that will follow.
According to the Heidelberg Model, in order to establish the diagnosis, we must define the signs and symptoms according to certain principles:

Constitution - gives us the functional properties of the individual and his inner nature, primarily based on their phenotype. The posture, tone of voice, facial expression and body are some aspects that characterize the person and allow you to define its constitution. Chinese medicine believes that the physical structure modifies the performance of the man, his feelings, and functions indicate the likelihood of showing certain symptoms (Greten, 2008). Thus, constitutional signals considered "normal" in an individual, may be a manifestation of another's disease, whose constitution is different. The corresponding phases express constitutional types and represent the person's tendency to express a predominant pattern.
The different types constitutional can be synthetically characterized by following expressions: the Hepatic (Wood) would like to live in an arena (see Apendix 1). The Cardiac (Fire) would like to live on a stage (see Apendix 2). The Pulmonary (Metal) seeks life in a sanatorium (see Apendix 3). The Renal (Water) would like to live in a fortress, looking for security (see Apendix 4).

In the social context, the Hepatic is the entrepreneur and pragmatic leader, the Cardiac is the creative and the chaotic, the Pulmonary is the understanding kind with a team spirit and symbiotic, and the Renal, is the administrative, the bureaucrat (Greten, 2008).
We can facilitate the determination of the constitution of a person through prior determination of the Yin or Yang type and relate them to their corresponding phases respectively.

Agent - is seen as a power (vector) function, which causes changes in the functional properties of the subject, producing and inducing groups of clinical and diagnostically relevant signs (orbs). Agents can be divided according to so called “climatic excesses” or in to emotions as follows:

– External agents: Algor (cold) Humor (moisture), Ventus (wind), Ardor (flushing),
Aestus (summer heat), Ariditas (dryness).

– Internal agents: Voluptas (Joy), Ira (Anger), Maeror (Sadness), Timor (Fear) Pavor (Shock).

– Neutral agents: overwork and stress, bad eating habits, smoking, alcohol, drugs, infection, excessive sexual activity, accidents and injuries.

Orb - refers to the clinical manifestations of one stage are a group of signals relevant for diagnosis indicating the functional state of a body island and of the corresponding conduit.

Guiding Criteria – they can be understood as the interpretation of the regulation of the body based upon the physiology of the four regulatory models which each of the components will allow to perform a functional diagnosis (Porkert, 1985). Current understanding of these features clearly shows that these criteria are an extension of vegetative regulatory system, including processes such as microcirculation (algor / calor), defense mechanisms and the relationship between the cellular (yin) and the regulatory processes (yang). They are:

– Depletion/Repletion, evaluates the clinical signs that in TCM is believe to be originated primarily from the qi and Orbs. In Western terms: a poor population of cells can be stimulated excessively vegetatively causing vegetative clinical signs as they were appointed under repletion. Therefore, a stage of near collapse with functional signs may appear similar to depletion

– Calor/Algor, evaluates the signs that Chinese medicine is thought to originate from the effects of xue ("blood") which is the second functional power ("energy") of Chinese medicine. In Western terms, these signs are due to overactivation mechanisms that involve: the microcirculation and local interdependent mechanisms of plasma, blood cells, endothelium and functional tissue of the organ; this is an activation of body fluids, at least in some part of the body; and can evoke vegetative and systemic responses in the context of fluid distribution, supply and circulation of fluids (i.e. changes in thirst, urination, blood supply and heart rate).
In summary, clinical signs of this type may be referred to humorovegetative with respect to the origin. Signs of overactivation of xue (effects on the microcirculation) are generally described as Calor, lack of signs of functional microcirculation are called Algor.

– Extima/Intima evaluates the signs that in Chinese Medicine are believed to originate from the effects of a pathogenic factor (agent) that invades the body from the outside. The most common underlying pathophysiological model is the model of six stages (Shang Han Lun). This is the process of the agent algor damaging the body. It is therefore called algor laedens theory (ALT).

– Yin/Yang, evaluates signs which, according to Chinese Medicine, distinguish between primary deregulation (yang) or deregulation due to structural deficiency (yin).
If a functional tissue is deficient, it will be excessively up-regulated to achieve proper function. As this over activation cannot be kept for a determined amount of time functional deficiency appears.

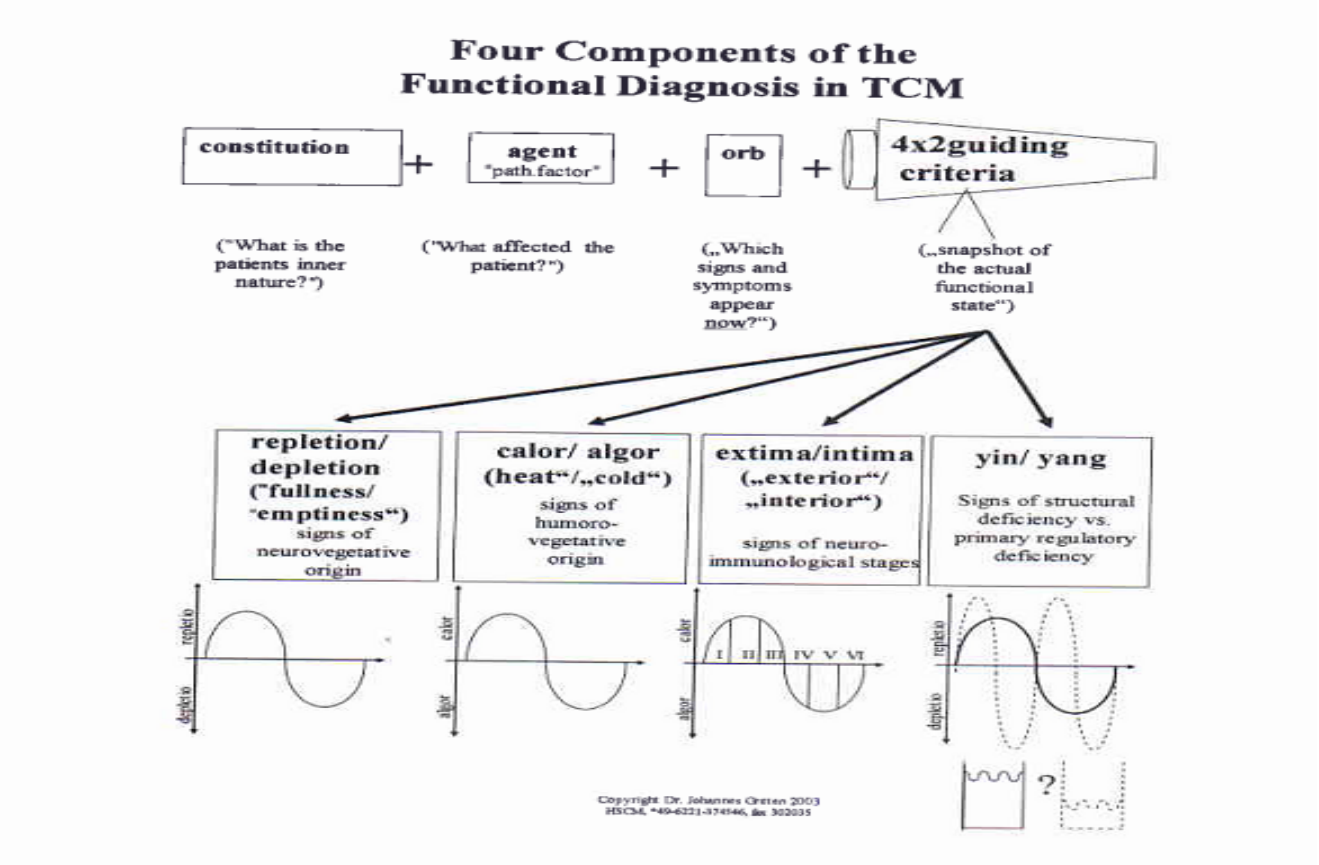


Figure 7 – The four components of the functional diagnosis in TCM. In *Understanding TCM*, Greten (2008)

The differential diagnosis in Chinese medicine results from joining all data relevant and pertinent, schematically represented and collected by the following assessment tools:

Observation - body shape, movements and actions; different parts of the body - (skin, face, lips, tongue and mucous membranes), sound and tone of the voice, cough, and breath odor.

Interrogation - addressing history, possible disturbances accumulated in the past, information on lifestyle, diet and appetite, elimination, perspiration, menstruation, temperature sensation, local pain and modality of pain.

Palpation - skin, limbs, hands, chest, abdomen, acupuncture points, radial pulse (constitutes a fundamental method to validate and / or verify some of information collected in the diagnostic and thereby assess the state of internal systems, Qi, Xue and Yin).

2.5.2 - PATHOGENESIS ACCORDING TO THE HEIDELBERG MODEL

The individual expression of life is the result of the balance of bodily energies. Health results from the harmonious balance between the various entities and forces the body and its environment. When this balance is disturbed the disease manifests itself.

According to the Heidelberg Model the mechanisms that can cause disease / deregulation are four:

– Difficulty in the transition between phases

The transition between phases takes place through a successive form of different functions. In a pathological way the same functions of a phase / orb become dominantly present. This is called a dominant sign and is then seen as separate of the continuum and that leads to pathological symptoms of an orb from which that sign specifically belongs. (Greten, 2008)

– Imbalance between agonist / antagonist

When we are faced with an imbalance of agonist and antagonist, one of the phases will be in excess relative to each other, leading to a predominance of signals characteristic of this phase (Greten, 2008)

– Excess agent

If a particular agent is present continuously the respective phase also will be produced continuously, leading to an excess of the corresponding vector. (Greten, 2008).

– Yin deficiency

Describes a structural weakness and lack of supletion means that manifests as an unstable regulation with an extreme course in the regulatory curve (Greten, 2008).

There are four types of yin deficiencies that appear commonly in clinical practice:

– Yin deficiency "sui generis" (lack of "functional tissue");

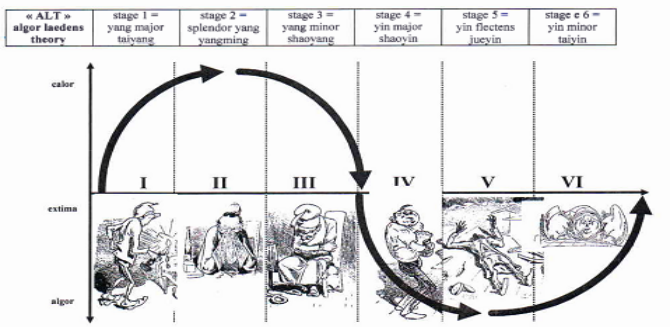
– Lack of xue ("lack of microcirculation within the tissue");

– Lack of body fluids (jing ye) ("missing middle factors" such as the dehydration);

– Lack of jing ("cellular functional deficits" such as weakened cell core- ie. radiation, chemotherapy - or genetic defects).

2.5.3- ALGOR LEADENS THEORY

The stages of ALT are characterized by specific clinical signs, the understanding of which is an absolute must for the professional practitioner of TCM. The ALT belongs to lesser known theories of TCM. It describes six layers of functional powers of defenses within the body, that agents have to overcome when trying to invade it. These six layers six energy trigger defense mechanisms, which could lead to six stages of energetic defense, (six technically different forms of energy).



« ALT » algor laedens theory	stage 1 = yang major taiyang	stage 2 = splendor yang yangming	stage 3 = yang minor shaoyang	stage 4 = yin major shaoyin	stage 5 = yin flectens jueyin	stage e 6 = yin minor taiyin
Symptoms of phases „catchword"	„Sciatic and ear pain"	„Acute sinusitis"	„Hot-cold-nausea-phase"	„Mucus and bronchitis"	„Flat-down-phase" („pneumonia")	convalescence
Involved conduits and orbs	V - IT	IC - S	F - TK	P - L	H - PC	R - C
Linked conduits and orbs	R - C (2nd circuit)	P - L (1st circuit)	H - PC (3rd circuit)	IC - S (1st circuit)	F - TK (3rd circuit)	V - IT (2nd circuit)
Exemplary decoction	Dec. Ephedrae, Dec. Ram. Cassiae	Dec. Ancillae Yue	Dec. Bupleuri	see text	see text	see text
Variation I: energetic factors determining the course	Lack of xue and defensive-qi: more prone to phase 1	Additional ventus: even acuter calor	Weakness of orthopathy (qi): faster transition into phase 4	Lack of qi worsens the course, as P und L are qi-dependent	More xue: part of hepatic yin, therefore worse, if xue deficient	Yin (body substance) is decisive
Variation II: „outside-inside hopping" or „inside-outside-hopping"	If yin is extremely weak: direct transition into stage 6 possible	If lack of qi and depletion of the centre: direct transition into stage 4	If lack of qi and xue: direct transition into stage 5	"sinu-bronchitic syndrome" (transition from stage 4 to stage 2)	stage 5 may go over into stage 3, i.e. as a form of recovery in pneumonia in the elderls	In stage of recovery: i.e.still aching limbs of algor kind (1. stage)
Variation III: add. ventus	All phases tend to show more signs of yang, repletion and especially more CALOR!!					

Figure 8 – Algor Leadens theory. In *Understanding TCM* Greten (2008)

The six forms of energy are:

1- **Qi Defensivum**. Resides within the Extima outside the conduits and creates a first barrier of defense against external attacks.

2- **Qi in the conduit**. It's the Qi the within the conduit system.

3- **Xue in the conduit**. Xue is guided by Qi which are in the conduit system, and at the same time heats, nourishes and moistens the tissues. The heating effect in the tissue is needed to expel the agent algor out.

4- **Qi in the body island**. Qi which is within the Intima, a general name to the entire interior of the body where the functions of the orbs are generated in respective parts of the body ("islands" that are named according to the organs which lie approximately in the same region)

5- **Xue in the body island**. It's a substantial portion (yin) of the body islands with warming functions, thus activating functionally and enhancing properties.

6- **Yin or functional tissue itself**, in western terms the cell subpopulation.

And the six defensive layers are:

1- **Yang Major.** Greater Yang. The yang here is bigger than in the third defensive layer, so in comparison to Yang Minor the yang here progresses and the vector has an upward movement. It also shows that the yang of the body is still bigger than the invading algor. (Greten 2008)

2- **Splendor Yang**. The Overshining Yang. An expression that shows that the natural reaction (calor as a form of yang energy) may be excessive and therefore symptomatic. By this it is said in a western sense that the

reaction to an agent for example a virus produces more symptoms than the virus itself. Thus the overactive, splendorus expression of yang. (Greten 2008)

3- **Yang Minor**. Minor Yang. The term expresses that the reactive calor (yang) is regressive so the agent is bigger and the yang is then minor. Another expression for this stage is the pivot or turning point stage because here the yang (calor, extima) and the yin (algor, intima) chase each other like Tom and Jerry, leading to alternate feelings of cold and warmth. (Greten 2008)

4- **Yin Major**. Greater Yin. The expression shows that the agent has now penetrated the intima (yin) and as left the extima (yang) behind but still the yin is still bigger than in the 5th layer and generally bigger than the agent. (Greten 2008)

5- **Yin Flectens**. Vanishing Yin. In certain cases, during a course of a disease the defense (yang) produced by the yin is drastically diminished. This induces symptoms that are similar but not equal to a sudden yang deficiency and show the breakdown of Earth functions (orthopathy). This is called the flexus state, in which reactivity has almost vanished. (Greten, 2008)

6- **Yin Minor**. Minor Yin. Here the is less energy than in 4th stage in the intimal defense mechanisms but is a turning point were orthopathy is reestablished turning the vector upwads to the target value, representing, in a loose sense, regeneration.

2.5.4 - PAIN ACCORDING TO HEIDELBERG MODEL OF TRADITIONAL CHINESE MEDICINE

According to TCM, pain is interpreted as an obstruction to the passage of energy in the conduits that occurs in a specific area of the body, which may be due to a condition of repletion or depletion. The obstructed element can be the circulation of Qi and Xue and the manifestation of the impaired energy flow is pain. Acupuncture operates as a system that modifies the imbalances by use of needles at specific points, which aim to restore neurovegetative functions through the intervention on conduit flow.

All four mechanisms can lead to disease according to TCM, and which were addressed in this study, may also cause pain and are an excellent tool to assess pain of an individual patient. Given cases of chronic pain over time are involved more than one of these mechanisms, since it is a complex disorder involving several mechanisms and even recording synaptic patterns of pain in the brain called the memory pain, ie, the brain has a capacity to adapt both to function as dysfunction, which specifically in the case of pain can mean vegetative dysfunctional circuits and paths are stored in the brain, are stabilized by the construction of synapses and used preferably towards natural circuit pain free. The pain process becomes self-determined and independent, like a vicious circle.(Greten, 2008)

Pain may start a neuronal pathway. This is then stabilized by synaptic formation, and in some cases is even myelinated which leads to metabolic changes in transmission and causing pain (Greten 2008).

The neuronal pathways of activated functions are compared to vegetative and sensory nerves caused by pain and in Chinese medicine are often explained through dysfunctional patterns as orbs, stages of ALT or patterns that resemble agents (Greten, 2008).

Pain shapes the body - causes functional changes in the body that consequently lead to structural changes (morphological) and / or constitutional that cause pain and often manifest themselves in altered constitution of the individual and reduce the Yin, ie dysfunctions (heteropathy) (Greten, 2008).

The development of pain is even more favorable towards the presence of certain cofactors: lack of qi, xue, fluids and Yin (Greten, 2008).

Chronic pain often manifest signs and symptoms of yin deficiency, reactive calor, events of yang nature (which can lead to yin deficiency, since, the yin and yang consumes too exhausted mind and body), and emotional disorders as Ira or Maeror - the most common emotional change caused by pain and depletion (exhaustion) (Greten, 2008).

The main pathogenic agent associated with chronic pain is the algor allowing us to conduct the diagnosis by ALT and their orbs. Other external agents involved may include Ventus and humor, the latter emerges as a sign of general functional decompensation (Earth) (Porket, 1983; Greten, 2008).

The emotion Maeror can counteract with anger by the need for balance antagonist. Maintaining emotion Maeror, blocks the orb Pulmonary main responsible for the distribution of "Qi", this blockade by repletion or depletion, manifests itself in pain. If on one hand the Maeror leads to the need of the individual symbiosis family and social system to which it belongs, on the other, this symbiosis need to automatically produce more anger (reactive), by their need for autonomy, but if anger was expressed, destroy the symbiosis. So anger is suppressed in the background.

The suppressed anger, pain and sadness constant internal block all success in life, personal goals, ability to individualism, ie, blocks the phase Wood, increases muscle stiffness, causing even more pain. The maintenance of pain exacerbates the need for intimacy and help the other can lead to the development of self-rewarding pain. (Greten, 2008)

These are many consequences in the reflection of the unconscious and development of voluntary dependent behaviors and lack of individualism. The mechanism mentioned here may sometimes change people from a cardiac constitution (the most common in Portuguese population) to a pulmo-felleal constitution, revealing that some hyper emotionality in youth (voluptas) was present in a deficient yin (Greten, 2008).

2.6 - PLANTAR HEEL PAIN. A TCM PERSPECTIVE.

In the Traditional Chinese Medicine approach on treating heel pain most authors like Lu (2008) recommend basically the same acupuncture treatment for pain caused by plantar fasciitis, subcalcaneal bursitis, calcaneal apophysitis, retrocalcaneal bursitis, and the so called Bi syndrome in TCM (usually a sign of rheumatoid arthritis) including all these conditions in a calcanodynia denomination and refers to them as conditions marked mainly by heel pain when it bears weight.

The points R3 and V60 included in the study by Tillu and Gupta (1998) and also recommended by other authors like Deadman (2011) are part of all treatments recommended by Lu (2008) for heel pain.

According to Yanfu (2000) pain over the heel is generally attributed to renal depletion. The locations is obviously the most important feature of this observation as the renal conduit runs from the basis of the foot to the internal maleolus and medial aspect of the calcaneus. The plantar and medial side of the foot and leg belong to the yin side of the body and as the renal orb represents the status of the yin the allocation is proper.

As the Water phase to which the renal orb belongs stands for regeneration and also the yin, and PHP is considered a degenerative condition, the point selection should reflect the balancing of yin (renal) and yang (vesical) within the Water phase and supletion of yin.

So, in my opinion it makes more sense to speak about the treatment of plantar heel pain rather than specifically plantar fasciitis or every other similar degenerative conditions, that cause heel pain when it bears weight, separately if we are dealing with a TCM based acupuncture treatment.

Even the conservative treatments of conventional medicine are alike for all those conditions so it is simpler to talk about a plantar heel pain syndrome of mechanical origin as the Clinical Practice Guideline on Heel Pain Panel of the American College of Foot and Ankle Surgeons suggests.

This however does not exclude the possibility that the proposed acupuncture protocol used in this study and based on TCM concepts could not be used in any of the other conditions that cause plantar heel pain, as it was designed to

relieve foot and heel pain as acupuncture effects on pain have clearly a broad usage.

What it does exclude is individual TCM differential diagnosis. The task of recruiting patients is difficult and to randomize patients using TCM individual diagnosis can challenge the feasibility of this study. Therefore a more simple approach was chosen to try and make this study executable in the time that was given, and still ensure maximum reliability of outcomes and objectives.

Another aspect to be considered in the differential diagnosis in TCM is the type of pain.
Although individual diagnosis is always the best approach, if we consider only the type of pain and choose the right intervention for it, results do show, as most of the musculoskeletal complains result from external agents (algor, ventus, humor).
In the case of PHP the pain is usually of stabbing or tearing nature which indicates xue stasis or algor in the agent step (what affected the patient?) of the diagnostic procedure.

The right intervention is then leopard spot technique or other type of mild bloodletting for the xue stasis, and moxibustion for the algor. Sometimes both interventions are used as algor and xue stasis often come together.

3. - STUDY DESIGN

3.1-TARGET STUDY

Prospective, randomized, controlled study designed to determine the effects of acupuncture in plantar heel pain.

3.1.1 Legal and administrative procedures

Approval by administrative board of the Centro Hospitalar de Entre Douro e Vouga
Approval by ethical commission of the Centro Hospitalar de Entre Douro e Vouga
Approval by the Head of the Anesthesiology Service, Head of the Orthopedics Service, and the Coordinator of the Pain Unit of the Centro Hospitalar de Entre Douro e Vouga
Written informed consent by all patients.

3.2 - Objectives

3.2.1 - General Objective:

– To evaluate the effects of acupuncture on plantar heel pain.

3.2.1 – Secondary Objectives:

– To compare specific effects of a TCM based acupoint selection versus nonspecific effects of puncture out of the known conduit system in PHP.

– To compare optimal types of acupoint stimulation by using the same TCM based acupoint selection.

3.3-METHODS

3.3.1-Recruitment

60 patients should be selected for this study. They will be diagnosed by the Department of Orthopedics with plantar heel pain of mechanical origin when standing.

Patients are then referred to the Anesthesiology Department for further evaluation of the inclusion exclusion criteria, possible contra indications for acupuncture, give written informed consent and are randomized in to two thirty elements groups. From the first thirty, ten will be selected to compare VA to CA with five elements each.

3.3.1-Inclusion Criteria

- Collaborating with evaluation and follow-up;
- ASA physical status classification I and II;
- Patients refer heel pain and plantar when standing;
- Ability to understand and provide consent procedure;

3.3.2-Exclusion Criteria

- Presence of heel pain/plantar area due to fracture, rheumatic, infectious, neurologic or immunological disease, diabetic foot;
- Patients with chronic use of neuromodulators, opioid analgesics;
- Pregnancy;
- Pathologies and drugs that contraindicate the technique of acupuncture;
- Refusal of the patient to give consent;
- Allergic to metals;

3.4-Intervention

3.4.1-Control groups

Verum acupuncture group (VA) – Conventional Acupuncture with single use, sterilized needles. Treatment with R7, V66, and L6, on the affected foot.

Laser acupuncture group (LA) – Laser Acupuncture with LaserNeedle device. Treatment of the same points as group (VA) using a wavelength. of 685 nm, power density of 4.6 kJ/cm2 per point.

Control acupuncture group (CA) – Conventional Acupuncture with single use, sterilized needles. Puncture of three points on adjacent skin areas out of the conduit system

3.4.2- Acupuncture Points

Verum points
– R7 - Amnis Recurrens, L6 - Copulatio Trium Yin and V66 – Valis Comunicans Vesicalis

Sham Points
– Two points at the level of R7 and L6 located in the medial side of the tibial crest and a third point located between the 3rd and 4th toes proximal to the margin of the interdigital web.

See Appendix 5 and 6 for visual point locations

3.5-Parameters and measurements

- Visual Analogue Scale (VAS).
- Analysis with emed® pedography platform, of 18 parameters: total plantar force (N), total plantar area (cm2), and peak pressure value (N/cm2) and peak pressure percentage (%) for 8 different areas of the foot.
- Regular scale
- Follow up time of 3 weeks

3.6 - Intervention and measurement procedure

This will be a two fazed intervention. The first trial will consist of one single needling treatment to measure acute effects by pressure tolerance between VA and CA group.
In a second trial, the points of the group with the best result will be treated by conventional needling vs Laser acupuncture to find out about the optimal stimulation parameters twice a week over three weeks.

The measurements will be pre and post therapy for each session in all groups, in three moments.

1st- After the VAS scale inquiry, using a 10cm ruler with 0 meaning no pain and 10 the worst imaginable pain;
2nd- the patient standing up right, places the affected foot on the emed® pedography platform, and the other foot on a wooden board with the same height of the emed® pedography platform so as to maintain the two foot supports at the same level. Measurement starts. The patient remains still for 5 seconds. At this moment the patient shifts his weight bearing towards the affected foot and then returns to the starting position and stands still again for 5 seconds. End of measurement.

3rd- At the regular scale station the patient while standing is asked to execute maximum pressure on the scale with the affected foot. The maximum value in kilograms registred by the scale is then collected.

The patient then proceeds to a comfortable bed were the respective treatment is applied for 20 minutes. After the treatment is undertaken he or she then returns to the measurement stations and repeat measurement procedures.

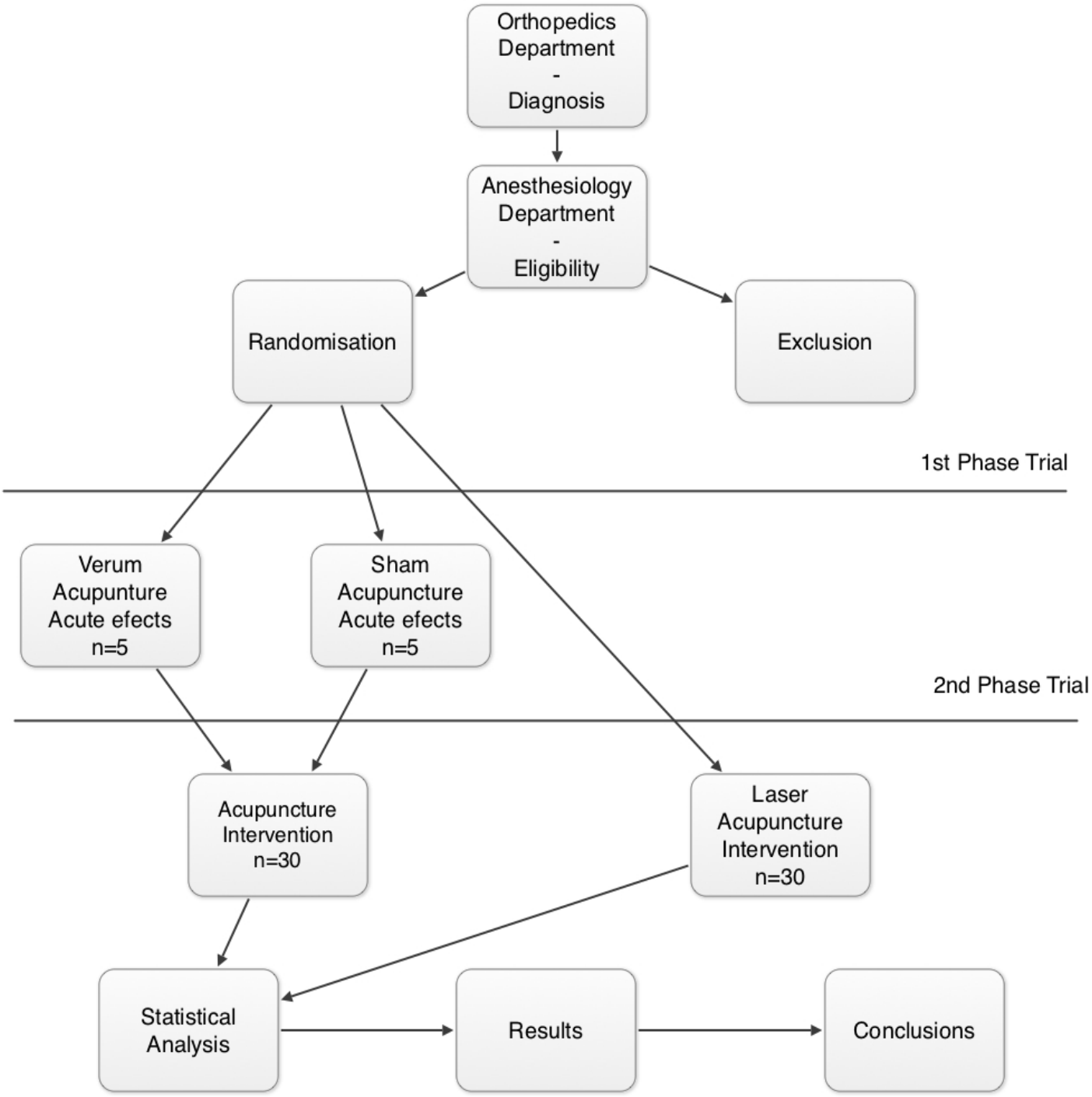
4- STATISTICAL ANALYSES

The results of measurements for the three groups are subjected to variance analysis in order to determine the existence or not of differences between the average values of selected parameters. Statistical significance is evaluated and weighed against the null and alternative hypotheses. Analysis will be applied to "One-way ANOVA" because the experimental design allows the combination of the type of group, and a single categorical independent variable, and the variables x, y and z are the multiple dependent variables.

Given the large number of variables can be applied to principal component analysis, in order to separate the groups and detect the relationship between structure variables. These will be selected based on the results of analysis of variance, noting that for the homogeneity of variances, checked with the Levene test. This will allow the reduction of variables, where the selected should justify much of the variability between groups, improving separation and making easier the perception of the factors that will be predominant on the basis of the distinction of the groups.

The interpretation of results should then be directed towards the secondary objectives analysis of Verum versus Control and Verum versus Laser.

5-.FLOWCHART


Orthopedics Department - Diagnosis
Anesthesiology Department - Eligibility
Randomisation
Exclusion
1st Phase Trial
Verum Acupunture Acute efects n=5
Sham Acupuncture Acute efects n=5
2nd Phase Trial
Acupuncture Intervention n=30
Laser Acupuncture Intervention n=30
Statistical Analysis
Results
Conclusions

6- EXPECTED RESULTS

The proposed study is currently an ongoing process. As explained before it has a previous approval by the heads of the hospital departments involved (see Appendix 7) but to this date no data was collected.

It is hoped that this study should contribute to the gathering of valid data regarding the treatment of Plantar Heel Pain using Traditional Chinese Medicine concepts and interventions.

Has suggested by the proposed hypotheses significant differences between Verum and Sham group should be expected. Comparison between and Verum and Laser should show some differences but it remains doubtful if there will be statically significant.

Positive correlation between VAS scores, platform data and regular scale are expected to be found

Objective data should demonstrate a better distribution of plantar pressures towards the rear and medial foot, and increased ability to exert vertical pressure has pain is diminished.

In clinical terms the Verum group should be more effective in relieving pain on weight bearing and could improve foot mechanical impairment in patients with Plantar Heel Pain.

7- CONCLUSION

Objective study designs for evaluation of potential acupuncture effects in PHP should be developed with the following features:

- A prospective randomized study design
- Proper controls by comparison of hypothesized verum points with comparable skin areas located out of the systems of conduits
- Finding optimal stimulation parameters such as the comparison of laser acupuncture and needling techniques.
- Double-blinding should be introduced according to the Heidelberg double-blinded essay.
- Measurement by pain assessment before and after treatment should include pressure algometry as too introduce an objective physical parameter in pain assessment as well as VAS.

The present study project approaches 4 of the features except double blinding. It has been submitted in the Centro Hospitalar de Entre Douro e Vouga, was approved by the Head of the Anesthesiology Service, Head of the Orthopedics Service, and the Coordinator of the Pain Unit and pre-recruitment measures have been taken at the time point of this master thesis deadline.
The present staff limitations of the Centro Hospitalar de Entre Douro e Vouga, do not allow the gathering of required help for a double-blind study as the entire medical and nurse staff available for cooperation are familiar with acupoints and TCM concepts.

The complexity of data analyses in pressure algometry, and good quality controls also require a careful consideration, and to advance for a higher degree of validity some preliminary studies are necessary to ensure maximum reliability of outcomes.

The study is designed to reveal basic data for a prospective randomized double-blinded study in the future with optimal stimulation parameters and point selection, and objective measurements by pressure algometry in addition to VAS

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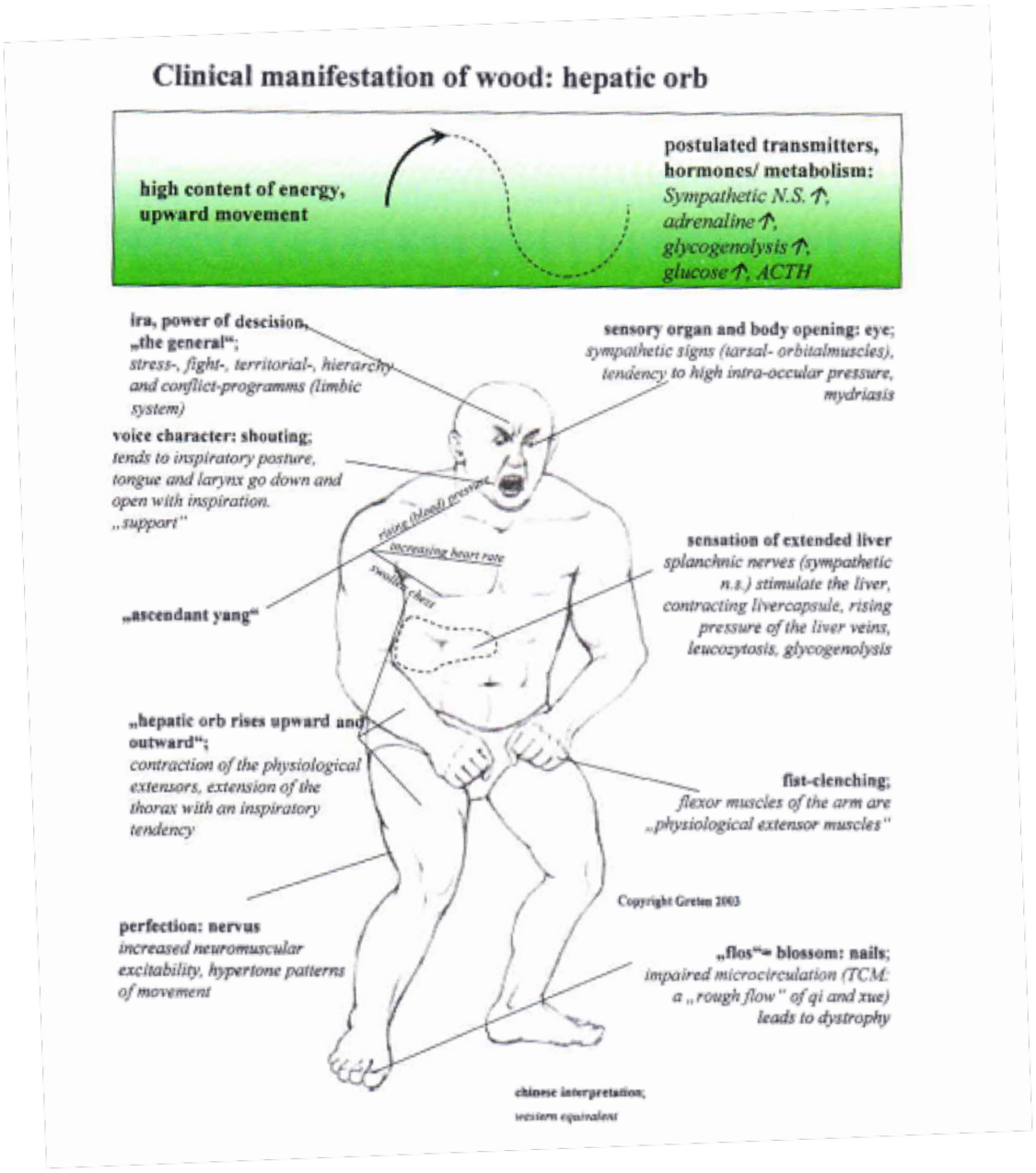
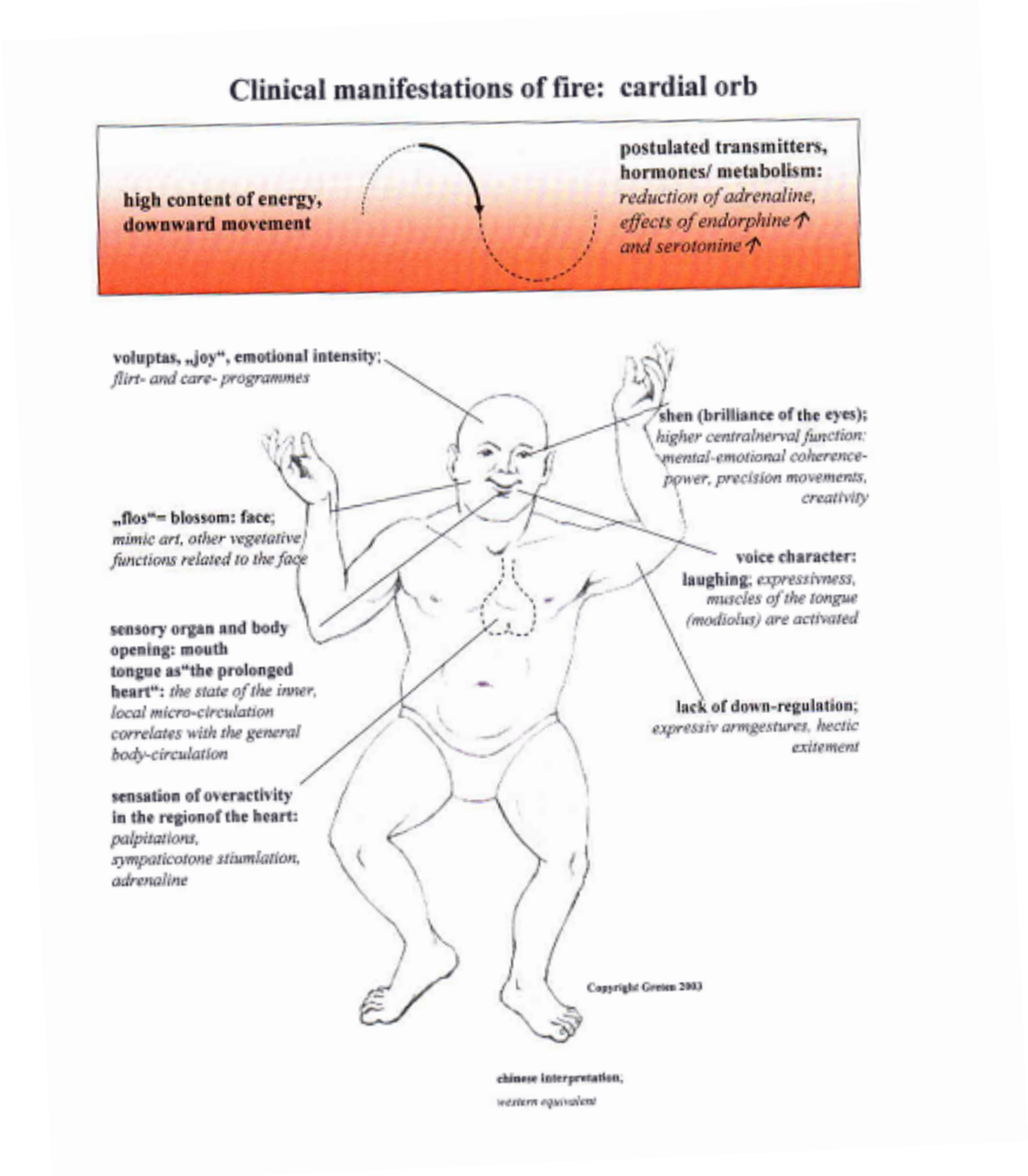
9- APPENDIX

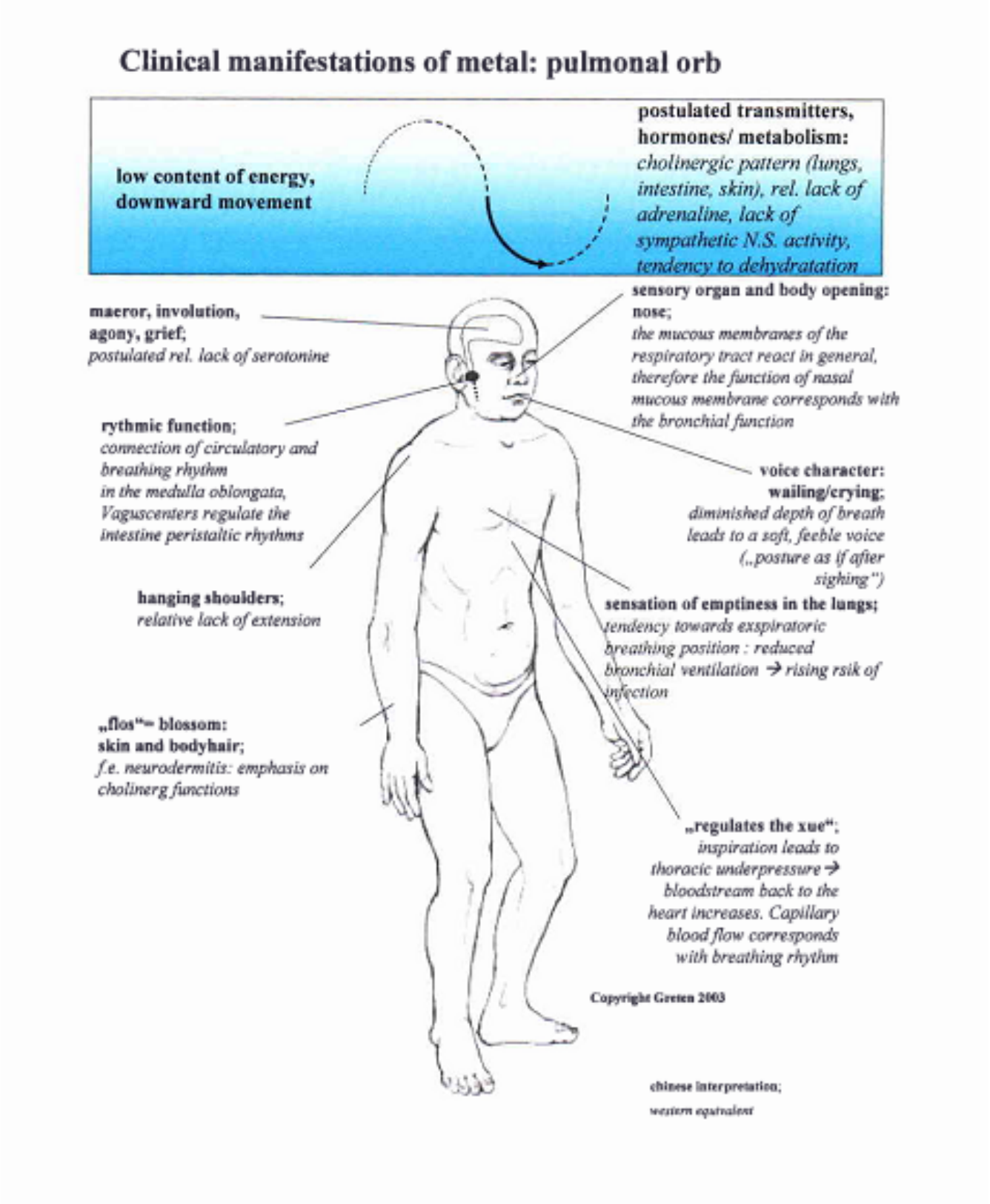
Appendix 1 – Wood type constitution. In *Understanding TCM* Greten (2008)



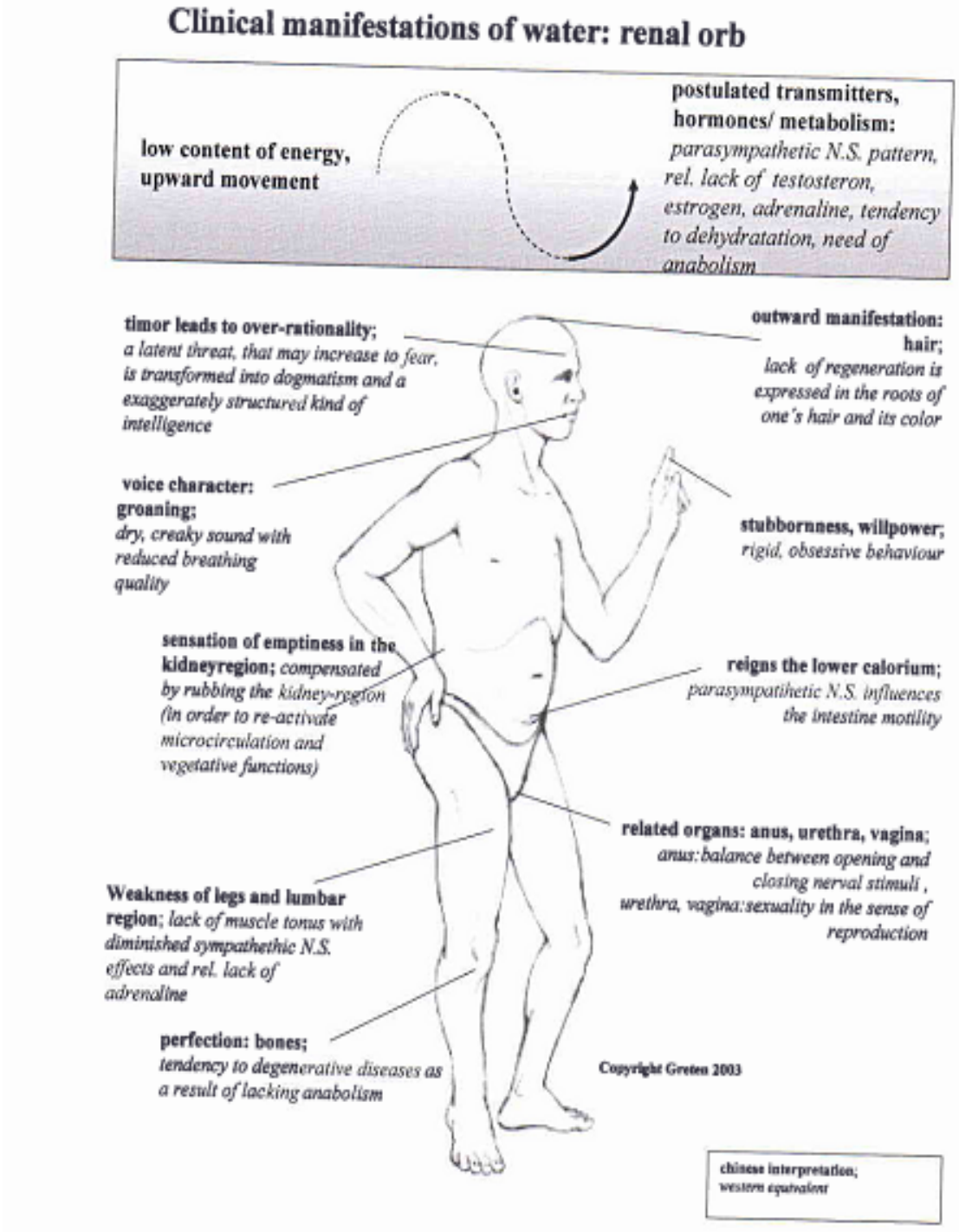
Appendix 2 – Fire type constitution. In *Understanding TCM* Greten (2008)



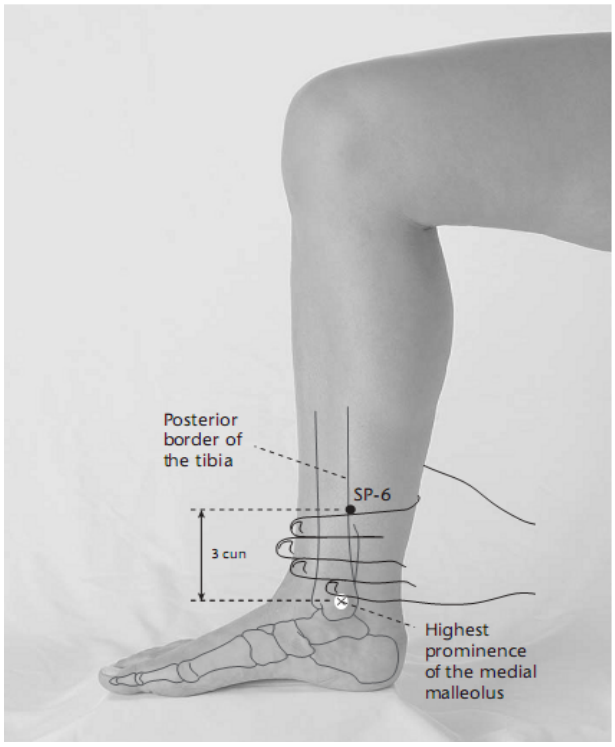
Appendix 3 – Metal type constitution. In *Understanding TCM* Greten (2008)

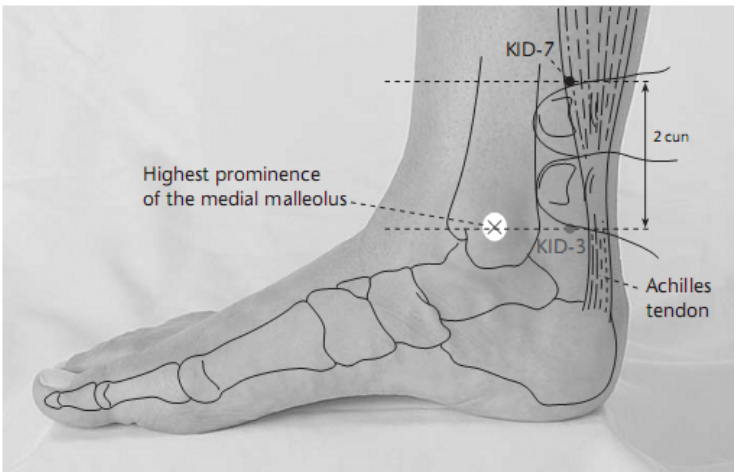


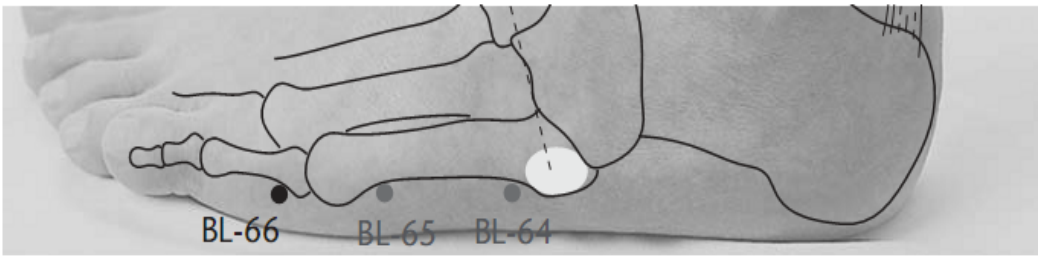
Appendix 4 – Water type constitution. In *Understanding TCM* Greten (2008)



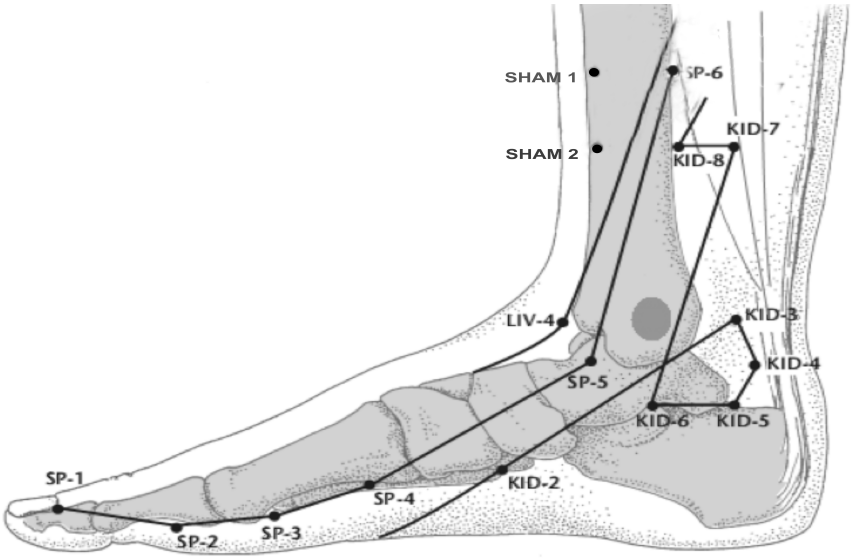
Appendix 5 - Verum points location. In Focks C.: *Atlas of Acupuncture*. Elsevier 2008

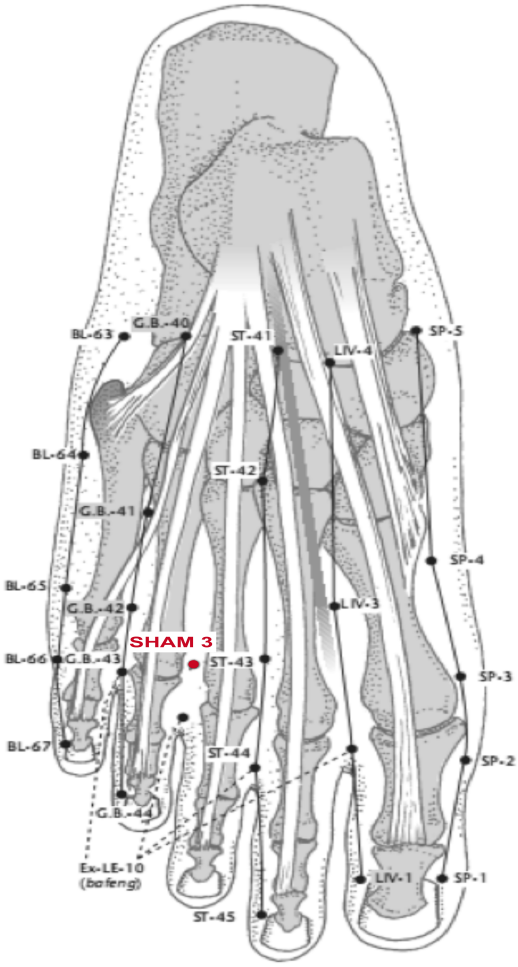




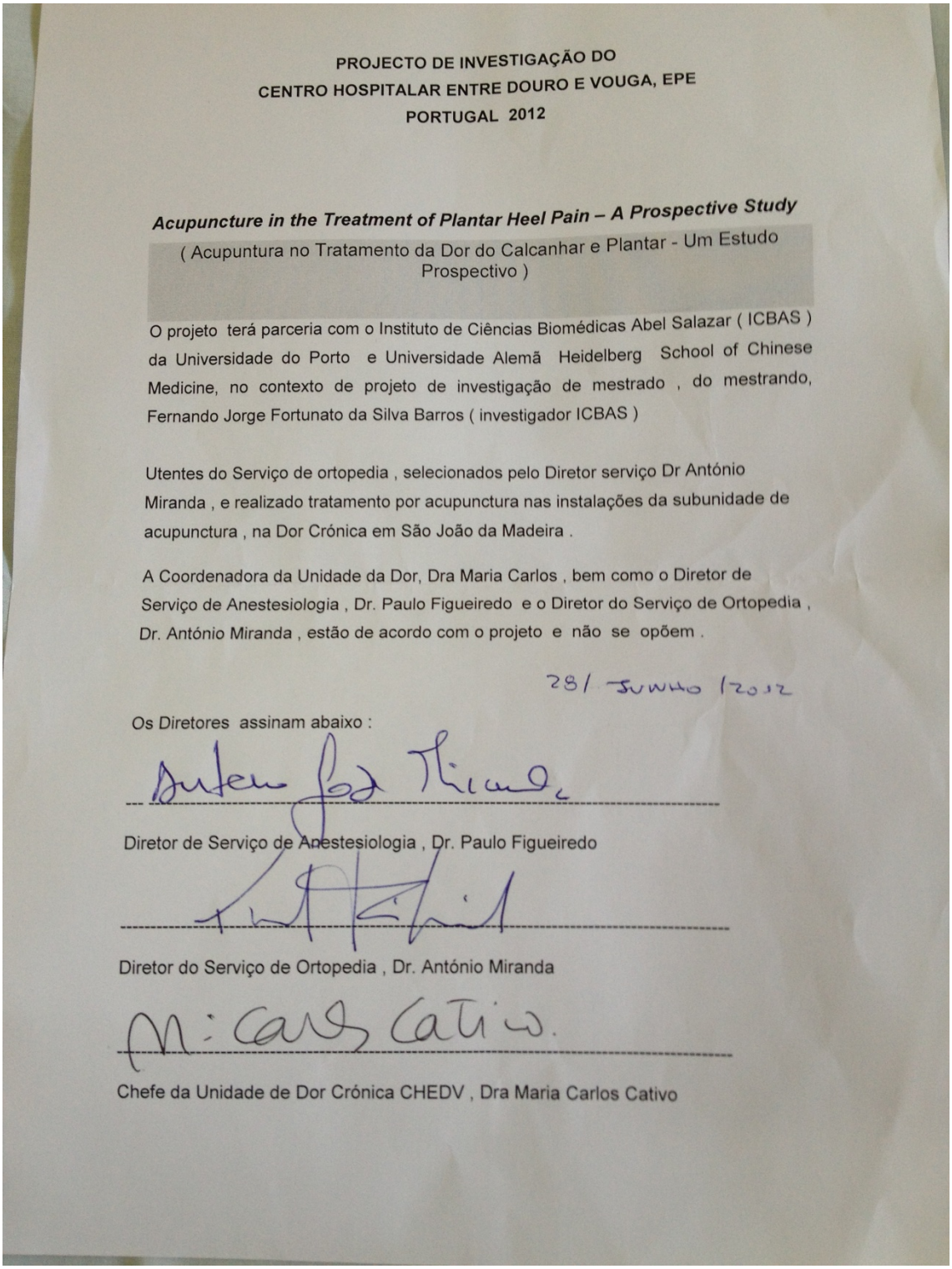


Appendix 6 – Sham acupoints location. In Focks C.: *Atlas of Acupuncture*. Elsevier 2008 *(adapted)*





Appendix 7 - Centro Hospitalar de Entre Douro e Vouga, Head of the Anesthesiology Service, Head of the Orthopedics Service, and Coordinator of the Pain Unit's approval.



PROJECTO DE INVESTIGAÇÃO DO
CENTRO HOSPITALAR ENTRE DOURO E VOUGA, EPE
PORTUGAL 2012

Acupuncture in the Treatment of Plantar Heel Pain – A Prospective Study

(Acupuntura no Tratamento da Dor do Calcanhar e Plantar - Um Estudo Prospectivo)

O projeto terá parceria com o Instituto de Ciências Biomédicas Abel Salazar (ICBAS) da Universidade do Porto e Universidade Alemã Heidelberg School of Chinese Medicine, no contexto de projeto de investigação de mestrado , do mestrando, Fernando Jorge Fortunato da Silva Barros (investigador ICBAS)

Utentes do Serviço de ortopedia , selecionados pelo Diretor serviço Dr António Miranda , e realizado tratamento por acupunctura nas instalações da subunidade de acupunctura , na Dor Crónica em São João da Madeira .

A Coordenadora da Unidade da Dor, Dra Maria Carlos , bem como o Diretor de Serviço de Anestesiologia , Dr. Paulo Figueiredo e o Diretor do Serviço de Ortopedia , Dr. António Miranda , estão de acordo com o projeto e não se opõem .

28/ JUNHO /2012

Os Diretores assinam abaixo :

Diretor de Serviço de Anestesiologia , Dr. Paulo Figueiredo

Diretor do Serviço de Ortopedia , Dr. António Miranda

Chefe da Unidade de Dor Crónica CHEDV , Dra Maria Carlos Cativo

Appendix 8 – Consent form

DECLARAÇÃO DE CONSENTIMENTO

Considerando a "Declaração de Helsínquia" da Associação Médica Mundial (Helsínquia 1964; Tóquio 1975; Veneza 1983; Hong Kong 1989; Somerset 1996 e Edimburgo 2000)

Designação do estudo (em português):

Eu, abaixo-assinado, _____(nome completo do doente), compreendi a explicação que me foi fornecida acerca do meu caso clínico e da investigação que se tenciona realizar, bem como do estudo em que serei incluído. Foi-me dada oportunidade de fazer as perguntas que julguei necessárias, e de todas obtive resposta satisfatória.

Tomei conhecimento de que, de acordo com as recomendações da Declaração de Helsínquia, a informação ou explicação que me foi prestada versus os objectivos, os métodos, os benefícios previstos, os riscos potenciais e o eventual desconforto. Além disso, foi-me afirmado que tenho o direito de recusar a todo o tempo a minha participação no estudo, sem que isso possa ter como efeito qualquer prejuízo na assistência que me é prestada.

Por isso, consinto que me seja aplicado o método, o tratamento ou o inquérito proposto pelos investigadores.

Data: _____/_____/20__

Assinatura do paciente: _____

Os investigadores responsáveis:

Nome: Marcos Pacheco da Fonte

Assinatura:

Nome: Fernando Jorge Fortunato da Silva Barros

Assinatura: