

Is Acupuncture an Effective Adjunctive Treatment for Osteoarthritis of the Knee?

A Literature Review.

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Abstract

Background: There is no current cure for osteoarthritis of the knee. Acupuncture is part of traditional Chinese medicine, a system that emphasises the body's healing ability. Recent trials have suggested acupuncture can ease pain and stiffness. Clinical trials focus on the effects of acupuncture and not on how the treatment works. Difficulties exist when applying scientific research methods to acupuncture treatment however evidence is emerging that can inform future research and treatment.

Methods: A systematic and reproducible critical literature review was carried out. Research trials of acupuncture as a treatment for osteoarthritis of the knee conducted since 1992 are discussed. Conclusions and recommendations are made.

Results: There is a lack of available information in orthodox medicine concerning the beneficial effects of acupuncture on osteoarthritis of the knee. This results in acupuncture remaining an underused and undervalued treatment option. Clinical trials show an accumulation of evidence supporting the use of acupuncture to deliver significant improvements in knee function and pain relief with minimal side effects and the potential for a close patient/practitioner relationship that can be beneficial in the treatment of a chronic condition.

STOP PRESS

Witt et al (2006) of the University Medical Centre, Berlin published results from a randomised, controlled trial of 3,553 patients with chronic pain due to OA of the knee or hip. Results were in line with trials reviewed in this study. As a result, the German Federal Committee of Physicians and Health Insurers is considering the possibility of covering costs of acupuncture treatment for these conditions. If approved, it may lead to acupuncture treatment becoming a routine medical option for the treatment of OA in Germany

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1. Introduction

Osteoarthritis (OA) is the most common joint disorder causing pain and stiffness as the cushioning cartilage between the bone joints wears away. The cause is often unknown and primarily related to aging. McCormick et al (1995) suggest OA may be present in some form in over 1000 million people in Europe with 2.02 million adults in the UK consulting their GPs every year with symptoms attributed to OA. The burden placed on the National Health Service (NHS) is well known. Mauer (1979) suggests more than 550,000 people in the UK have X-ray evidence of moderate to severe OA in their knees. The Department of Health logged more than 56,562 knee replacements between 2004-2005. The price to the NHS is high, with GP consultations alone estimated to cost £307 million in 2000 (source: Office for Health and Economics 2001). The Arthritis Research Campaign's publication *Arthritis: The Big Picture* (2004) draws attention to the high cost of prescribed drugs (£341 million in 2000), rheumatology in UK hospitals (£259 million in 2000) and hip and knee replacements (£405 million in 2000) bringing the total cost of OA to the UK NHS and Social Services to £5.5 billion in 2000.

There are also economic implications. Arthritis and related conditions, as discussed in *Arthritis: The Big Picture* (2004) are the second most common cause of days off work for both men and woman in the UK. The Office for National Statistics & Department of Work and Pensions estimates working days lost in 1999-2000 were equivalent to an £18 billion loss of production.

Within the total numbers in the UK affected by OA, it is estimated that 550,000 have moderate or severe OA in their knee joints. As knee OA becomes increasingly common, chronic and costly to treat, as well as unpleasant for the sufferer, alternatives and complements to drug therapy or surgical intervention are attracting the attention of patients. Amongst alternative

treatments purporting to benefit knee OA, acupuncture has been subjected to a number of trials, with preliminary studies showing some interesting, potentially encouraging results.

The western medical profession is reluctant to endorse any complementary therapy that cannot stand up to rigorous research trials. Methodological issues in acupuncture trials are well documented. Kaptchuk (2001) notes attempts to measure acupuncture against western medicine on western medical terms puts the more subtle benefits of acupuncture at a disadvantage. Blinding practitioners, delivering sham acupuncture without needling and measuring patient benefits in qualitative as well as quantitative terms have all proved elusive. However, as side effects compromise effectiveness of drug therapy, numbers of sufferers and health care costs increase and patients themselves seek complementary alternatives, a multidisciplinary integrative approach to treating knee OA deserves consideration.

In the context of the western and eastern view of knee OA, this study seeks to critically examine the research available concerning acupuncture as a beneficial treatment for knee OA. By highlighting not only the strengths and weaknesses of research to date, but also drawing on the strengths of acupuncture practice to treat the whole patient, the study will seek to recommend a place for acupuncture as part of a combined conventional, holistic and self management programme of treatment for sufferers of knee OA.

2. Aims and Objectives

2.1 Aims

To conduct an extensive and up to date literature review of evidence for the effectiveness of Traditional Acupuncture as an adjunctive treatment to osteoarthritis of the knee and to see how this informs acupuncture practice.

2.2 Objectives

- Provide a brief overview of the western and eastern medical approach to treating knee OA.
- Identify the body of research that exists on the use of acupuncture in treatment of knee OA.
- Critically and systematically examine relevant research, identifying strengths and shortcomings.
- Identify common outcomes and discuss potential for future research.
- Provide evidence that the author has understood the process of critically appraising work done by others in order to develop as a research minded practitioner and provide a summary of what has been learnt from this academic process.

3. Methodology

To evaluate the effect of traditional acupuncture on knee OA, a number of alternative methodologies could be used. Tarling et al (1998) suggest methods have specific purposes:

- *Collect the best possible evidence to support or refute a particular argument*
- *Minimise the risk of bias in the collection of evidence*
- *Be practical and efficient*
- *Conform to certain ethical positions in relation to the collection of evidence from human subjects*

(Burns and Grove 1987 pg 335-359 1998 cited in Tarling et al 1998 pg 53)

3.1 Selecting an appropriate methodology

3.1.1 Quantitative Research

Vickers (1995) suggests that the advantage of quantitative research is that it can provide information which is directly applicable to practice. The author considered a survey of a cross section of patients via questionnaire, with carefully chosen questions to elicit information which could be gathered and presented, concerning the efficacy of acupuncture for knee OA. However, this approach was rejected because of the relative inexperience of the author in this field, time constraints associated with being an undergraduate researcher and ethical issues.

3.1.2 Qualitative Research

A questionnaire could have been devised to collect narrative information rather than numerical data. Vickers (1995) suggests this approach can be prone to misconception and individual bias. Perspectives of the effectiveness of treatment vary and Robinson et al (1988) advise using a third party, for example research teams or consultants, to avoid personal bias or inhibited

participants. This was beyond the scope of the undergraduate researcher. Whilst quantitative methods may make the benefits of acupuncture difficult to express in percentage points or simple yes and no answers, the qualitative approach is also restrictive. Knafelz et al (1984) suggests that the absence of a standard format for reporting qualitative research can make validity difficult to assess. Qualitative research offers an array of methods including case studies and interviews. It is an increasingly favoured method of examining relationship and therapeutic outcomes of acupuncture treatment; however conducting qualitative research presents similar challenges to the undergraduate researcher as does a quantitative approach and was therefore rejected.

3.1.3 Literature Review

Utilising the volume of published literature to conduct a critical and intellectual evaluation offers the author a controllable approach to conducting an undergraduate dissertation.

Hart (1998) defines a literature review as:

'The selection of available documents (both published and unpublished) on the topic, which contain information, ideas, data and evidence written from a particular standpoint to fulfil certain aims or express certain views on the nature of the topic and how it is to be investigated, and the effective evaluation of these documents in relation to the research being proposed'

(Hart, C 1998 pg13)

A literature review allows the undergraduate researcher a manageable approach in terms of costs, time and outcome. In conducting a literature review a systematic, explicit and reproducible method is used as stated by Fink (1998) to evaluate and interpret an existing body of recorded work. By utilising the latest published research, the study can make an appraisal of the published work on acupuncture as a treatment for knee OA. Recommendations may then be made for further research.

Accepting the limitations of time, experience and ethical issues inherent in producing an undergraduate dissertation and in recognition of the volume of existing research, the author has selected a literature review as the most suitable methodology.

3.2 Literature Search

The author was only able to utilise literature in the English language.

College of Traditional Acupuncture (CTA) Library, Hatton

An initial search of the CTA library allowed the author to consider the classical texts of traditional acupuncture, contemporary works on *Bi syndrome* (congruent to OA in the eastern medical rubric according to Pei-Lin et al 1994, Maciocia 2005, Deadman 1983 and others) and a selection of general texts on western medicine and traditional acupuncture.

Oxford Brooks Electronic Library

A literature search, using the criteria 'acupuncture' 'osteoarthritis' and 'knee' was made on the following online data bases, both respected for their broad based sources:

- AMED
- CINAHL

Other internet data bases searched using the same criteria included:

- Medline
- Cochrane Library
- Google Scholar

- AOL
- NELH
- Bandolier
- British Medical Journal
- British Library
- National Institute for Health
- National Institute for Clinical Excellence

These represent the main sources of internet databases for quality medical information.

Internet and electronic library searches produced a total of 38 research papers, abstracts of these research papers and articles.

A search of the quality on line journals was also conducted using the same key words 'acupuncture', 'osteoarthritis' and 'knee'.

- The European Journal of Oriental Medicine
- The Journal of Chinese Medicine
- Acupuncture in Medicine

These publications are well respected and represent the main sources for journal articles on acupuncture and related subjects.

This search added a further 1 research paper and 4 articles that met the author's selection criteria.

The final selection of papers to be reviewed was based on:

- Acupuncture and knee OA being the central theme
- Acupuncture treatment delivered via needling not acupuncture or predominantly electro acupuncture
- A minimum of 25 participants in the sample group

This left the author with a total of 13 research papers and articles.

3.3 Methodological problems

As only papers written in or translated into English could be considered, there may be vital omissions in literature about this traditionally non-western practice. The original proposal was based on the wealth of material available. Some papers did not meet the final selection criteria. By adopting a broad approach more literature was initially identified than was manageable. The final selection of papers encompasses the essential works in English and a systematic review was possible in the time available.

3.4 Statement of bias

The author is a student acupuncturist and is aware of the potential for bias. Every effort has been made to remain impartial.

3.5 Ethical considerations

The author is not aware of any ethical considerations

4. Literature Review

4.1 Osteoarthritis of the Knee from the Western Perspective

Joint disorders are classified as non-inflammatory or inflammatory. Thibodeau & Patton (2002) note that osteoarthritis is the most common non-inflammatory disorder of moveable joints.

Osteoarthritis is the name given to degenerative joint disease. It primarily affects weight bearing joints and involves the progressive breakdown of articular cartilage, resulting in damage to the underlying bone. Wheelless' (2006) define osteoarthritis as a gradual process of destruction and regeneration.

Causes can be primary (idiopathic, resulting from 'wear and tear' with onset most common in the sixth decade) or secondary, which can result from a variety of causes including obesity, pathogens (e.g. cytokines, cellular toxic mediators), infective bacteria, trauma, ligament injury, genetic or developmental abnormalities and some metabolic or endocrine diseases (e.g. acromegaly).

Knee OA more often affects the medial compartment than the lateral as the weight bearing axis of the knee results in this compartment carrying approximately 60% of the load causing it to degenerate more commonly than the lateral compartment. As the knee collapses inward the condition often progresses at an exponential rate. (Appendix 1: Clinical Feature of Knee OA)

Western medicine cites five stages of osteoarthritis:

1. Breakdown of articular cartilage
2. Synovial irritation
3. Remodelling of bone creating osteophytes
4. Eburnation of bone and cyst formation
5. Disorganisation of the joint

(Dandy & Edwards, 2003)

This highlights the origin of osteoarthritis as a failure of articular cartilage to retain its healthy smooth surface, generating friction resulting in inflammation. The joint cartilage degenerates and new bone and connective tissue grows within it. Gasgoine (2001) suggests inflammation is minor and secondary to this process.

In the early stages, knee OA is diagnosed from reports of pain, loss of movement and altered function. There may also be swelling, crepitus, weakness and progressive deformity in the affected knee. As the condition worsens, radiological information shows pathological changes: narrowing of the joint space, alteration in the bone shape and formation of osteophytes (spur like bony outgrowths). Osteophytes may be the body's attempt to 'splint' the joint.

Apley et al (1993) notes pain is worse when the knee bears weight; after exercise joints stiffen. Night pain is another cardinal feature, often severely disturbing sleep. Pain may originate from damaged tissue within the joint and in surrounding muscles which have to work hard to maintain the stability of an unstable joint. Movement is slowly lost as osteophytes form. Because the knee is weight bearing, osteoarthritis here has a greater potential for pain and restriction than osteoarthritis in an upper limb joint.

Until knee OA becomes very severe, western treatment is orientated towards joint conservation and pain relief. In the early stages, patients are advised to keep active but to modify their

lifestyle to avoid activities that aggravate the joint. Walking sticks are encouraged and are most effective when used in the contralateral hand. In general, the advice given is *if it hurts, don't do it* (Dandy & Edwards 2003). Physiotherapy may be used to increase the power of muscles around the knee to compensate for the worn joint and to increase blood flow.

As knee OA progresses both analgesics and anti-inflammatory drugs become important. Their use is controversial as they do nothing to reduce the progress of OA. They act on the whole body and can result in unwanted side effects. Long term reliance on these drugs may not be in the patient's long term interests. Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen dominate current drug usage. Mori report 36% of arthritis sufferers use NSAIDs (ARC: The Big Picture 2000). Ibuprofen is available as an over the counter drug, making it difficult for the western physician to control a patient's dose, so statistics recording prescription usage can be very conservative.

Dandy & Edwards (2003) note NSAIDs are useful both to reduce pain and the inflammatory response within the joint. Whilst not improving the articular surface, where damage is irreversible, the response of the synovium to particles worn away from articular cartilage is reduced. Thus NSAID drugs can reduce the response of pain and stiffness felt following activity.

Almost all NSAIDs have the potential to cause gastrointestinal problems, renal problems and confusion and may not be a suitable therapy for elderly patients, who unfortunately form a large proportion of knee OA patients.

'Once you begin taking NSAIDs, you multiply by seven times your chance of being hospitalised due to gastrointestinal adverse effects.'

'In the UK, some 4,000 people die each year from taking NSAIDs – twice the number of deaths from asthma.'

(McTaggart, 1996, page 84)

NSAID drugs can also accelerate the progression of knee OA and so should be used intermittently and cautiously. Berman et al (2004) suggest NSAIDs may be ineffective and cause unwanted and dangerous side effects.

NSAIDs can depress chondrocyte activity and this may cause the disease to progress more rapidly, especially in weight bearing joints.'

(Dandy, 1989, pg 292)

Chondrocytes maintain articular cartilage by processing nutrients. They also modulate the articular cartilage matrix, providing much of its inherent strength.

Analgesics (such as paracetamol) reduce pain, but have no effect on the osteoarthritic process. NSAIDs and analgesics are often combined to give patients relief from the pain of advanced OA. Other prescribed medications include sleeping tablets and anti-depressants.

More recently, COX2 inhibitors have been used for pain control. They too have a marked side effect profile. COX2 inhibitors are related to standard NSAIDs and inhibit the COX2 receptor responsible for pain modulation located specifically in the joint. This group of drugs have less gastric toxicity but many have now been withdrawn owing to specific cardiotoxicity.

Steroid injections into the joint reduce inflammation, but leave underlying damage unchanged and are very painful. They have a temporary effect of variable duration and are not suitable for every case of knee OA. Ongoing use raises the risk of joint cavity infection.

Separate from drugs used for pain control are disease modifying agents. Glucosamine and Chondroitin Sulphate have been shown to be mildly effective in treatment of early OA, but have no effect on moderate or severe OA according to O'Rourke (2001). Oral Glucosamine and Chondroitin enhances the ability of articular cartilage matrix to hold water. Through rehydration it becomes less prone to damage.

When these conservative therapies are no longer sufficient and knee OA is progressively deteriorating, surgical intervention is considered. Not every patient is a candidate for surgery; many spend months on a waiting list. Surgical intervention relieves symptoms in some patients but is expensive and associated with significant levels of risk. In 2000, 35,351 total knee replacements were performed in the UK, and together with hip replacements the cost to the NHS was £405 million (OHE Health Statistics compendium 2001). The National Joint Registry (2006) indicates that over 85% of these joint replacements are performed because of either primary or secondary osteoarthritis.

Arthroplasty is the surgical reconstruction or replacement of a malformed or degenerated joint. It gives reliable, longlasting functional and pain relieving results (Laskin 2001). Generally 90% of individuals undergoing knee replacement operations have good or excellent results and 95% of modern knee replacement designs can be expected to last for more than ten years.

Treatment goals following knee replacement surgery include:

- Not requiring painkillers
- Sleeping normally at night

- Not requiring walking aids
- Ability to walk an unlimited distance
- Ability to carry out all activities of daily living independently.

However surgery is associated with risk and complications in knee replacement occur in between 5-10 % of cases ranging from trivial to life threatening.

The cost of a knee replacement to society is significant. Privately, costs may be £10,000 generating an NHS tariff of £5,600 with knee implants costing £1,500 - £2,000. The drain on NHS resources is considerable, with over 30,000 knee replacements carried out in the UK each year. (Pryke, 2007, Ipswich Hospital)

4.2 Osteoarthritis of the Knee and Traditional Acupuncture

A number of different styles of Traditional Acupuncture are practiced in the UK, of which the predominant are Traditional Chinese Medicine (TCM) and Five-Element Acupuncture. Both share a common fundamental basis but each places a different emphasis on the diagnosis and treatment of knee OA. In addition Western Medical Acupuncture is practiced by some members of the British medical profession.

Chinese medicine has a dynamic history. Its principles were documented in the *Neijing*, also known as *The Yellow Emperor's Classic of Medicine*, written in 221BC. Ni (1995) details how the *Neijing* suggests a holistic life where external factors such as climate and seasons and internal factors such as emotions and our response to them fundamentally affect health.

Hsu (1989) notes there is a broad tradition of medical knowledge growing from China at this time embedded in Daoist and Confucian philosophy. Stollberg, (2002) notes different styles of practice have grown from it. Some elements of this traditional medicine were introduced to the West in the 1960s where they became disconnected from their philosophical background and adapted to offer a medical counter-culture.

Traditional acupuncturists believe that the body is permeated with channels, referred to as *Meridians* or *Jingluo*. The *Meridians* are thought to contain *Qi* which can be translated as energy and is defined by Hicks et al (2004) as the life force present in every living thing. The *Meridians* run over the body, connecting extremities with internal parts, in a continuous circuit. Mann (1996) explains acupuncturists use fine needles to manipulate *Qi* at specific points on particular *Meridians* in order to regulate and balance *Qi*. Traditional acupuncturists believe that if *Qi* is balanced, the body is able to regulate and heal itself.

Traditional acupuncture theory results from an inductive process of reasoning that begins with observation. Hart (1998) suggests it is not designed to produce certainty - observations of practitioners are open to interpretation. Kaptchuk (1974) explains an eastern perspective seeks to explain the process of health and disease as balance and imbalance. Thus when *Yin* and *Yang* (polar opposites) are balanced, there is health and when imbalanced, there is disease. (Appendix 2: *Yin-Yang* Theory)

4.2.1 Five Element Acupuncture

The teachings of Jack R Worsley have been influential in the growth of Five Element acupuncture in the UK and USA. He drew on *Meridian* theories, *Yin-Yang* theory and the theories of the *Five Elements* in classical Chinese texts such as the *Neijing*. Barnes (2003) notes he introduced a practice which placed the emphasis on emotional manifestations of the 5 phases. Kaptchuk (2000) describes the term '*Element*' in reference to a process, movement or quality of *Qi* with each *Element* having its own particular quality. Seasonal and other correspondences link nature and the external environment with changes taking place in the patient. Cycles and flows exist to explain the movement of *Qi* through the *Meridian* network and their interrelationships. These theories form the basis of a model seeking to explain how the processes of the body interact and support each other. (Appendix 3: Five Element Models)

Five Element acupuncture treats Knee OA by:

- Correctly assigning a *Causative Factor (CF)* to each patient
- Assessing the health of *Officials* via pulse and tongue diagnosis, and through the sensory acuity of the practitioner
- Assessing the correct level of treatment – body, mind, spirit or a combination.
- Needling points on *Meridians* corresponding to the patients *CF* using techniques to tonify or disperse the *Qi*.

- Considering *moxabustion* to nourish *Blood* and *Qi* and warm a cold patient.
- Use of *Cupping* and lifestyle advice to support treatment
- Offering supportive treatment on other *Meridians* as an adjunct
- Once treatment is established, using symptomatic point combinations such as Eyes of the Knee or Backmann Knee Points (Appendix 4: Eyes of the Knee and Bachmann's Knee Points)

Specific treatment of knee OA, therefore, becomes individual to the patient according to their *CF* and the practitioner will recognise imbalances in emotions as well in the body.

4.2.2 Traditional Chinese Medicine

TCM practitioners, as outlined by Maciocia (2005), seek to identify syndromes or patterns of disharmony from the presenting signs and symptoms. Kaptchuk (1947) explains that once signs and symptoms are expressed as a pattern of disharmony this will lead practitioners to select the appropriate treatment rationale.

Unlike Five Element acupuncture, there are accepted treatments for specific patterns of disharmony making TCM acupuncture treatments more predictable and therefore a more suitable modality for western researchers seeking to measure and evaluate effectiveness of acupuncture.

Vangermeersch (1994) explains that *Bi-Syndrome* is associated with rheumatism and therefore OA. Pei-Lin (1994) suggests treatment aims to activate the free flow of *Blood* and *Qi* by removing obstructions which are the source of pain. The *Neijing* classifies *Bi-Syndrome* into six types including location, severity and duration. The etiology of *Bi* was considered to be external pathogenic factors of Wind, Cold and Damp, i.e. climatic and seasonal factors. Hicks et al (2005) note that TCM practitioners recognise joint conditions may be due to problems in the

Meridian rather than at a deeper level in the body and therefore needling points local to the affected joint is an acceptable treatment protocol.

TCM acupuncture treats knee OA by:

- Identifying *Bi-Syndrome* and classifying it according to etiology
- Needling points on *Meridians* with a causal relationship to the diagnosis, with needle technique achieving the sensation of *De-qi*
- Using *Moxabustion* to nourish *Blood* and *Qi* and warm a cold joint.
- Using herbal medicine, Cupping and lifestyle advice to support treatment
- Needling symptomatic points as an adjunct

Deadman (1983) notes that TCM acupuncture, which focuses its primary therapeutic effect on the circulation of *Blood* and *Qi* is well placed to assist sufferers of *Bi syndrome*. Pei-Lin (1994) suggests the chief pathology is obstruction of the *Meridians*, causing *Qi* and *Blood* to have reduced circulation at the site causing malnourishment to bones and muscle. Macioca (2005) identifies obstruction as the source of joint pain. Static pain, as seen in knee OA is likely to indicate *Cold*. Any swelling in the joint indicates *Dampness*. (Appendix 5: Point Selection for *Bi-Syndrome* of the knee joint).

4.2.3 Western Medical Acupuncture

Medical acupuncture has been created to allow orthodox medical practitioners (predominantly doctors, midwives, nurses and physiotherapists) to use acupuncture without the requirement to study traditional Chinese medical theory. It represents an attempt by western medicine to understand acupuncture from a western scientific perspective. Stollberg (2002) notes there are radical differences which include the abandonment of traditional theories of acupuncture points and *meridians*, primarily because there is no physical verifiable anatomical basis, a replacement

of oriental medical theory with western pathology and disease concepts and a desire to understand the effects of acupuncture through the modern understanding of anatomy, physiology and biochemistry. Mann (1987) asserts *meridians* of energy do not exist, but the pathways may be neural and, as yet, unmapped by western science.

Western Medical Acupuncture treats knee OA by:

- Needling points proximal to the site of pain (either tender points, established points or a mixture) plus one or more distal points, using a standard needle technique as an adjunct to medication or surgery.

By leaving behind thousands of years of observation and tradition, Western Medical Acupuncture has difficulty in utilising acupuncture to its fullest potential. Although successful in treating some conditions in certain circumstances, this style of acupuncture often focuses on placing a needle at the site of a local physical symptom, with no attention to the overall wellbeing of the patient, limiting the degree of effectiveness. It is, however, suitable for use in a busy practice, where there is little time to spend with each patient.

Thus, as traditional acupuncture moved to the west, it became increasingly disconnected from its original philosophical and theoretical background. All styles of acupuncture in the west, Five-Element, TCM and Western Medical, have adapted to meet the needs of the patient and their lifestyle.

Western medicine seeks to find explanations for the effects of acupuncture and research has been undertaken in many areas. In the study of acupuncture on knee OA, the body of research undertaken has been based on TCM and Western Medical Acupuncture treatment. No comparable studies have been made of Five-Element acupuncture.

4.3 Review of Research

According to figures published by the Complementary Medicine Research Unit, one in ten of the U.K. population uses complementary medicine each year. Sierpina (2004) suggests this figure rises to 4 in 10 in the U.S. Complementary medicine offers knee OA patients another approach to treatment. Berman et al (2004) note that pharmacologic management of osteoarthritis is often ineffective. Drug therapies may cause unwanted or dangerous side effects. Acupuncture is believed to provide significant pain relief and improved function in patients with knee OA, but can this be proved through rigorous trials designed to test western medical treatments?

4.3.1 Christensen et al (1992)

This formed the first significant study. 29 patients, with a total of 42 osteoarthritic knees, were recruited and divided into 2 groups. Group A received acupuncture whilst group B served as a no-treatment control group. Both groups continued to take analgesic medication. Pain levels and analgesic consumption were measured after 9 weeks by investigators blinded to which group was A or B. Group A were treated with five retained needles around the painful knee and one at a distal point on the hand with a 20 minute treatment twice weekly for 3 weeks tapering to weekly to 9 weeks. Subsequently 17 patients from both groups continued with acupuncture treatment on a monthly basis for 3 months. The study concluded that Group A had a significant reduction in pain and analgesic consumption. Group A and B combined showed an 80% subjective improvement, with the greatest improvements in the worst affected knees. Researchers noted that beneficial effects of acupuncture were significantly better in patients who had suffered knee OA for the shortest time. Study conclusions were that acupuncture can ease discomfort whilst waiting for surgery and may even be an alternative to surgery, based on seven participants of their study deciding to cancel their surgery after participating.

The Christensen et al study is poorly constructed – primarily the sample size is too small and the placebo effect will be marked, as Group B and the evaluator were clearly aware that they were not receiving acupuncture. No explanation is given for the loss of some patients during the trial, and there is no mention of any controls applied to other therapies or medications patients may have taken up before and during the trial period. It is not possible to access the full paper thus details of the points used and needle technique cannot be analysed. There is no information about study funding, or the background of the researchers or qualification, experience and style of the acupuncturist. However, this study suggests further research is worthwhile and may have led to the progression of research in this area.

4.3.2 Puett and Griffin (1994)

The authors published a review of research into non-medical non-invasive therapies for hip and knee OA. The authors are western medical doctors from the Department of Preventative Medicine, Vanderbilt University, Tennessee, funded by the American Food and Drug Administration and Agency for Health Policy and Research. Two studies were reviewed. The first by Gaw et al is not directly relevant, as participants suffered OA in multiple joints. Although modest improvements were noted in the participants treated with acupuncture, improvements in some joints may have been masked by lack of improvements in others. The study by Christensen et al (1992) was also reviewed with Puet et al acknowledging the improvements in patients receiving acupuncture treatment and suggesting that these may be in part due to the placebo effect caused by a lack of sham treatment. They conclude that results for acupuncture (based on these two studies) are sparse and inconsistent and suggest more research and data is needed to evaluate acupuncture.

In the period 1999 – 2000, possibly stimulated by earlier research, four papers were published, three of which were linked to the University of Maryland School of Medicine in Baltimore USA.

4.3.3 Creamer et al (1999)

This study focuses on the role psychosocial factors might play in the response to acupuncture amongst knee OA patients. The researchers aim to address weaknesses in control group management and acknowledge the power of the placebo effect which Hart (1999) estimates may account for 40% of patient improvement.

'An abundance of evidence from clinical studies and experimental psychology indicates that subjectively assessed disorders such as migraine headache, back pain, rheumatoid arthritis and depression may respond very well to a placebo.'

(Price et al 1997 pg117)

The study acknowledges that acupuncture is found to help patients with knee OA but notes the response is highly variable. If patients likely to show the greatest response can be identified, the authors anticipate potential for a more rational use of acupuncture. By returning, 1 year later, to 37 participants of an earlier 8 week trial, using questionnaire, interview and physical examination, the researchers hoped to identify a relationship between demographic and psychosocial variables and the patient's response to acupuncture, as defined by reduction in pain and disability. In fact, the study did not identify this link, although there was a small non-significant trend to a better outcome for older better educated subjects. The study highlights a link between the duration of symptoms and the patient's response to acupuncture. The sample size was small, leading to a recommendation that future studies should confirm these results. Interestingly, this study found that patients with localised medial pain had a significantly better response in terms of pain and disability than those with more general knee pain. No explanation for this was offered as it fell outside of the aims and objectives of the study.

The evidence reviewed so far suggests acupuncture has a beneficial effect, most helpful to patients who have had a shorter duration of symptoms and that psychosocial factors are irrelevant. Patients with medial pain may respond better than those with general knee pain and

further studies will need to be larger and refined to include randomised double blind trials in order to satisfy modern medical research criteria. Hart (1999) suggests OA responds well to the placebo effect. The role of the placebo effect is often used by orthodox medicine to reduce the weight given to a positive outcome; however this effect may represent a self healing force entirely consistent with Traditional Acupuncture theory.

4.3.4 Berman et al (1999)

Progressing from earlier work, the authors explored acupuncture as an adjunctive therapy for knee OA at the Maryland School of Medicine. Their study begins to address many of the weaknesses of earlier work. 73 patients were recruited with knee OA causing them pain and dysfunction. Randomly assigned, one group received acupuncture treatment twice weekly for 8 weeks whilst remaining on their analgesic medication and not amending their regime to include any other therapy that may have benefited their knee OA. Acupuncture treatment was carried out in the TCM style based on a diagnosis of *Bi Syndrome*, using local and distal points of Gb34, Sp9, St36, St35 and extra point *Xiyan*. Distal points used were Bl60, Gb39, Sp6 and Ki3. (Appendix 6: Point Locations and Indications). Details of needle technique and duration are provided. The second group remained on medication and were offered acupuncture treatment after 12 weeks.

Results indicate that those randomised to acupuncture had improvements in their knee OA based on self scoring using the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) and Lequesne indices compared to the group who continued existing treatment only. Significant differences were seen at 4 and 8 weeks. At 12 weeks (4 weeks after ceasing acupuncture treatment) there was a slight decline in effect. No adverse effects were noted. There were no significant changes in the control group. In the acupuncture group, reductions were noted with pain decreasing slightly faster than dysfunction. At 8 weeks, the acupuncture group reported a 44% reduction in pain, which may be explained by the placebo effect brought about through interaction with, belief in and care and compassion from the

acupuncturist and their own expectation of treatment outcome, the acupuncture treatment, or a mixture of the two. 15 people (20.5% of the total group) failed to complete the trial. No information is provided to identify how many left from each group, weakening the study's results. If these patients left the acupuncture group, it would imply they did not receive a benefit from treatment. It is possible (although unlikely) that a potential maximum of 41% of the acupuncture group may have left the study before its completion, thus invalidating the published findings.

Creamer et al concluded that acupuncture is an effective and safe treatment (no significant adverse side effects were reported) for patients with knee OA and can be considered as an adjunctive therapy to conventional care. The effects of acupuncture are inextricably bound to the potential for a placebo effect when patients self score their pain and disability. However, under the restrictions of a small randomised trial, the results are encouraging and within 12 months Ezzo et al (2000) published a systematic review of acupuncture for knee OA, evaluating trials in order to identify areas for future research.

4.3.5 Ezzo et al (2000)

The researchers evaluated trials of acupuncture for knee OA by control group type, to assess methodological quality, particularly looking at the prevalence of low quality trials associated with positive outcomes, to document any adverse effects and to identify aspects of the patient or procedure that are associated with a positive outcome.

The conclusion reached in trials conducted to date was that evidence suggested acupuncture might play a role in the treatment of knee OA, primarily for the reduction of pain. Improvements noted in physical function were inconsistent. Existing research did not demonstrate acupuncture to be as effective as other treatments, due to insufficient evidence. They note that receiving acupuncture is more beneficial to pain and function than remaining on

a waiting list, but cannot rule out spontaneous improvement or the placebo effect as factors. When acupuncture is compared with sham acupuncture, however, there is stronger evidence that real acupuncture is more effective at controlling pain, which suggests that the analgesic effects cannot be explained by the placebo effect alone. Difficulties with administering sham acupuncture include inadvertently eliciting an analgesic response. The authors suggest sham acupuncture needs to be both minimal in terms of very superficial needling, and distal to the points utilised by the true acupuncture group.

There is a clear recommendation that future research is both worthwhile and requires a refinement in protocol. Additionally the authors note that trials to date do not replicate Traditional Acupuncture treatment, which is individual to the patient and not commonly administered so intensively. They acknowledge the evidence and suggest acupuncture may play a role in treating knee OA, however recommend further research to define optimal acupuncture treatment and assess acupuncture combined with other modalities.

4.3.6 Tillu et al (2001)

Accepting the premise that acupuncture is effective in increasing function and decreasing pain, Tillu et al (2001) investigated unilateral versus bilateral acupuncture in knee OA at Bedford Hospital, marking the first U.K study. 44 patients awaiting total knee joint replacement surgery for advanced knee OA were recruited. Patients were randomly assigned to two groups. Group A received acupuncture to the most affected knee only, Group B to both knees. Information is given on needling style and duration, but not on acupuncture style which could be either Western Medical or TCM. Points selected were Sp9, Sp10, St34, St36 and distal point, LI4 (Appendix 6: Point Locations and Indications). All patients received weekly acupuncture for 6 weeks. A blinded observer assessed knee function before treatment and at 2 and 6 months using the HSS knee score for pain and function. No adverse effects were noted and both groups showed statistically significant improvements in both subjective and objective parameters. At 6 months, 13% of participants left the trial (2 from Group A and 4 from Group B), 2 due to illness

and 4 went forward for their operations. Of the 38 patients remaining no significant differences were recorded between the two groups suggesting unilateral acupuncture is as effective as bilateral acupuncture as a treatment of knee OA.

4.3.7 Tillu et al (2002)

Tillu et al continued their work with a second study evaluating the effect of acupuncture on knee function in advanced knee OA. 75 patients were randomly allocated to two groups. Group A received acupuncture (points used were again Sp9, Sp10, St34, St36 and LI4) whilst Group B received no treatment. (Appendix 6: Point Locations and Indications). 4 patients (5%) failed to complete the trial, 2 due to needle phobia and 2 for reasons unknown. Acupuncture was delivered by a medical acupuncturist. Group A received acupuncture at weekly intervals for 6 weeks. Before commencing treatment, all patients were assessed for pain and function using the HSS score. The same evaluator reassessed all patients using the same score at 8 weeks. Group B recorded similar scores before and after the trial. Group A recorded a similar score to Group B before the trial, but recorded statistically significant reductions in their pain and function scores at 8 weeks.

The research conducted by Tillu et al is useful as an indicator for future research, but not scientifically rigorous. The lack of double blinding of patient and evaluator exposes their work to bias and the placebo effect. The study size is small, and the outcome expressed only in general terms. However, the study supports the findings of Christensen et al and Berman et al and notes that its findings may serve as a basis for further research.

4.3.8 Aiping et al (2001)

The Acupuncture Research Clinic of Singapore (Hongmaoquiao Community Hospital) also published research in 2001 led by Aiping. 109 knee OA patients were recruited into a study utilising a TCM approach. Points St34, Sp10, Ex-LE 4, Ex-LE 5 and St36 were needled (details of needling style are provided), with *Ahshi* points (Appendix 6: Point Locations and

Indications). If cold symptoms were diagnosed, *moxibustion* or heat lamps were used. *Cupping* was employed after needling. There was no control group, or blinding of patients or evaluators. Treatment was administered every other day for 10 sessions. Patients self scored therapeutic effects, classifying their improvement in pain and function into one of 3 categories (markedly effective, effective and ineffective). The authors suggest a total effective rate of 97%. They further breakdown this result to show a stronger therapeutic effect in patients who had suffered knee OA for less than 1 year. The study also noted the use of analgesics at the end of treatment, recording 85% of trial patients stopped taking analgesics altogether, 11% reduced their dose to occasional and 4% remained on the same dosage.

Although results appear persuasive, there are flaws in design and execution of this study. In the absence of a control group, positive benefits to patients participating in a medical trial or any spontaneous improvements cannot be comparatively measured. Lack of blinding is likely to promote the placebo effect in patients and bias in evaluators. Self scoring of pain and function by the patient is open to bias, and additionally weakened by the option of only 3 broad categories of self scoring.

4.3.9 Felson (2001)

As interest in and attention to acupuncture grew, David Felson, writing in the American publication *Arthritis & Rheumatism* (2001) made a plea for more evidence in alternative treatments for OA. He notes that some alternative therapies may be genuinely effective in OA whilst others are no more efficacious than a placebo. Common methodological errors include an absence of an intent-to-treat analysis, focus on evaluating only those patients who complete the trial and failures to conceal the allocation of patients prior to randomisation. He notes that non pharmacological trials in the U.S. are not controlled by the Food and Drug Administration, increasing the likelihood of fraudulent data. He asserts that well performed large, high quality trials can provide trustworthy evidence to guide therapy and patients will be well served if all OA trials adhere to these rigorous standards.

Available research, at this point, highlights the potential of acupuncture as an adjunctive therapy, but results are far from conclusive, because of the poor quality of many studies. Marcus (2002) comments that alternative medicine for sufferers of arthritis are aggressively promoted by the media, alternative health practitioners and some doctors. He notes that some proponents consider alternative medicine should be accepted and integrated into orthodox medicine based solely on empirical evidence. Others, notably the National Center for Complementary and Alternative Medicine (NCCAM) at the Maryland School of Medicine, maintain that the safety and efficacy of alternative modalities should be evaluated by randomised controlled trials. It seems clear that whilst some patients may be motivated to self refer for acupuncture treatment, any integration of acupuncture into orthodox medical treatment will only result from the outcome of scientific study.

4.3.10 Witt et al (2003)

A German Study, financed by social health insurance funds at the request of the German Health Authority, took a much larger sample of 300 patients with knee OA and randomised them into 3 groups, 150 assigned to acupuncture, 76 to minimal acupuncture and 74 on a waiting list for acupuncture. The study sought to minimise the placebo effect by informing participants that the study aimed to compare two styles of acupuncture testing which is more effective for knee OA. Real acupuncture was delivered with points selected from a choice of St34, St35, St36, Sp9, Sp10, Bl40, Ki10, Gb33, Gb34, Liv8, extra points *Heding*, *Xiyan*, and distal points Sp4, Sp5, Sp6, St6, Bl20, Bl57, Bl58, Bl60, Bl62 and Ki3, (Appendix 6: Point Locations and Indications) thus for the first time using a more flexible choice of points. Treatment was given 12 times over 8 weeks with follow up to 52 weeks. Minimal acupuncture was superficial insertion, no manipulation using 3 nonacupuncture points distal to the knee. At the end of the trial all patients receiving real or sham acupuncture believed they had received real acupuncture. Results are subject to intent to treat analysis and primarily measured using the WOMAC score at week 8

Results show a significantly better outcome for patients receiving real acupuncture. In addition, 52% of the real acupuncture group achieved a 50% or better reduction in their WOMAC score compared to 28% in the minimal acupuncture group and 3% in the control group. Analgesic consumption reduced in both acupuncture groups but not in the control group. After 52 weeks the improvements achieved by acupuncture were lost.

This study improves on previous work by increasing the number of participants, addressing the placebo effect, measuring analgesic consumption throughout the trial and making an attempt to measure acupuncture against minimal acupuncture and a control group. The results consolidate earlier finding that indicate improvements are available after 8 weeks of acupuncture, but that these improvements decline and are lost when treatment ceases.

4.3.11 Vas et al (2004)

This work made further improvements to methodology by introducing sham needling and patient and evaluator blinding. Their trial was randomised and controlled, studying 97 knee OA patients from the pain management unit of a public primary care centre in Spain. Study duration is identified as 2 years, but this is misleading as 23 months were spent recruiting participants. The trial lasted for 12 weeks and introduced a new aspect by considering the effect acupuncture might have on pharmacological treatment.

Patients were selected from three primary care centres and had clinical and radiological diagnosis of symptomatic knee OA. Additional selection criteria such as age, no previous experience of acupuncture, no concurrent serious conditions etc were applied. Patients were divided into two groups randomly by computer with evaluators blinded to the identity of the two groups. One group received acupuncture and diclofenac (a NSAID) and the other sham acupuncture and diclofenac.

During the trial patients were provided with weekly supplies of diclofenac and advised to take one every 8 hours but reduce the dose if symptoms improved. Unused medication was monitored. The acupuncture groups received weekly acupuncture for 12 weeks (11 treatments) from a doctor trained in medical acupuncture using local points Gb34, Sp9, Ex LE5 and St36, plus distal points Ki3, Sp6, LI4 and St40. Details of needling technique are given, (Appendix 6: Point Locations and Indications). The sham acupuncture group was also treated on the same points with the same frequency, but the needles were retractable, and did not pierce the skin. Good evaluation of the 9 patients who dropped out of the study is provided – 8 were in the control group and left predominantly because of lack of improvement and only 1 left from the true acupuncture group due to needle phobia, therefore not compromising the integrity of the results. Patients in both groups were scored using not only the WOMAC score, but also PQLC score (measuring changes in quality of life) and the Mann-Whitney U test for dropout analysis. SPSS was used to analyse the results by intention to treat.

Results show that acupuncture and diclofenac is more successful than sham acupuncture and diclofenac in reducing pain and improving function shown by reductions in the WOMAC scores for the group receiving true acupuncture. The paper claims patients in this group took 53.9 fewer diclofenac tablets than the sham acupuncture group, however there were 47 patients in this group at the end of the trial and this represents just over one fewer tablet per patient over a 12 week period.

Trial weaknesses appear to be a short duration and lack of follow up, inadequately expressed results in numerical terms, and small sample size. The study improved on some methodological weaknesses of earlier work by blinding participants and evaluators, attempting sham acupuncture for the first time and acknowledging acupuncture treatment aims to improve patients' overall wellbeing. Results therefore included quality of life changes, along with pain and function changes in the knee. Recommendations were to extend the observation period of future research, to evaluate the duration of improvement and establish treatment protocols.

4.3.12 Jubb (2004)

Also in 2004, results were published of a small study at Selly Oak Hospital, Birmingham led by Consultant Rheumatologist Ronald Jubb. Recruitment was based on strict inclusion and exclusion criteria to give a sample group of 30 patients well matched in age, OA severity as measured by VAS and WOMAC scores, disease duration and body mass index. This study randomly assigned patients to 3 groups. Group A received acupuncture treatment from a medical acupuncturist and ceased taking any anti-inflammatory or analgesic medication 7 days before the trial commenced. Group B received acupuncture and continued to take their analgesic medication. Group C acted as a control group, with acupuncture treatment offered after 5 weeks. Patients in Groups A and B received acupuncture twice weekly for 5 weeks from a medical acupuncturist using points Gb34, Ex Point Xiyian, Sp9, Sp10 St36, Bl40, Bl57 and distal points Liv3 and LI4. Information is given on needle technique, (Appendix 6: Point Locations and Indications). At 5 weeks a blinded observer administered the outcome measures with follow up 4 weeks later.

The outcome for the 3 groups was based on the Visual Analogue Scale (VAS) and WOMAC score, to determine changes in pain and function. 4 patients (13%) dropped out after 5 weeks. The authors do not identify from which groups they belonged, but give the reasons that 2 received no benefit from treatment, 1 did not wish to continue and 1 gained only temporary relief. If these patients were from Group A or B this would have an impact on the validity of the results. One patient in Group A continued to take anti-inflammatory medication and this data was excluded. Group C showed no change in pain scores whilst acting as a control group. After acupuncture treatment all 3 groups showed a significant drop in the VAS pain score, which was maintained by Groups A and B after 1 month. Similarly, the WOMAC scores decreased by more than 50% in groups B and C (after acupuncture) and by slightly less than this in Group A.

Once again, the study supports earlier findings that acupuncture has a beneficial effect, both alone or as an adjunct, in reducing pain and stiffness. This study is so small, with no attempt at blinding, that it can serve only as the basis for future work, however it is interesting to note that the strongest response came from using acupuncture as an adjunctive therapy.

4.3.13 Berman et al (2004)

In 2004, the University of Maryland School of Medicine published the largest and most scientific acupuncture and knee OA study to date. Berman, et al used their earlier studies as a springboard to take earlier positive results from flawed trials and go forward with a larger more scientific study. They focussed on the effectiveness of acupuncture as an adjunctive therapy for knee OA. The study was well received by the U.S. organisations National Institute of Health, US Department of Health and Human Services, National Center for Complementary and Alternative Medicine and National Institute of Arthritis and Musculoskeletal and Skin Disease (all in the USA) whilst in the UK it was promoted in complementary health publications and web sites and formed the central part of a BBC documentary on acupuncture presented by Professor Kathy Sykes, making many sufferers of knee OA aware of the potential of acupuncture for the first time.

In the trial researchers recruited 570 people with a minimum age of 50 who had an existing diagnosis of knee OA but had not previously received acupuncture treatment, had knee surgery in the preceding 6 months, or used steroids or steroid injections. Patients were randomised into 3 groups. Group A received acupuncture over a 26 week period, with treatment tapering off as the benefits were realised. Points were selected according to TCM protocol for *Bi-Syndrome*, and consisted of 5 local points (Gb34, Sp9, St36, St35 and Ex point *Xiyan*) and 4 distal points (Bl60, Gb39, Sp6 and Ki3). If only one knee was affected, acupuncture was used unilaterally, if both knees were affected, bilaterally (in accordance with Tillu et al 2001). Information was given on needling (Appendix 6: Point Locations and Indications). The remaining two groups served as controls. Group B received sham acupuncture which consisted of some needles

inserted into sham points on the abdomen and others being applied to the true acupuncture points but not piercing the skin. No information is given regarding how aware participants from Group B might have been that they were receiving sham acupuncture. Patients in the second control group participated in 6 group education sessions on self management of OA and received printed material by post and were therefore aware they were not receiving acupuncture. All the participants in this trial received their usual medications.

Measurement of any changes in pain and stiffness was made using the WOMAC Index with scores taken before the trial started, and at 4 8 14 and 26 weeks. Secondary assessments used were the patient global assessment, 6 minute walk distance and physical health scores of the 36-Item Short-Form Health Survey (SF-36).

The initial impression of results in this trial is persuasive. At week 14, WOMAC scores of Group A decreased by 40%. Pain scores decreased in Group A steadily and by the end of the study had, on average, decreased more than twice as much as patients in Group C. Knee function also showed a significant improvement in Group A and by the end of the trial was, on average, 40% greater than the average knee function of Group C. Researchers concluded that acupuncture seems to provide improvements in function and pain relief as an adjunctive therapy for knee OA when compared to credible sham acupuncture and educational control groups. But is this a fair conclusion?

On closer analysis, control Group B's knee function improved by 30%, compared to Groups A's 40% improvement. In the measurement of SF-36 Physical Function and the 6 minute walk there were no significant differences between Groups A and B. The delivery of sham acupuncture was weakened by the decision to needle the abdomen (risking some alteration in the flow of *Qi*) and the obvious sham acupuncture of the true points, risking bias in patient and evaluator. However, the greatest weakness in this study is the huge loss of participants by week 26; 43% of Group C, 25% of Group A and 25% of Group B. Not returning to a trial implies that

treatment made no difference, causing weakness in the data and methodology and leaving results open to question, especially when the placebo effect is taken into account.

Appendix 7: Characteristics of Included Studies.

5. Discussion

Knee OA is clearly painful for sufferers and expensive to manage. Side effects of drug therapies can be unpleasant and dangerous. Surgery is not always an option. As patients seek alternatives, interest in acupuncture has grown. Treatment offers the potential to reduce pain and improve function with no significant adverse side-effects. In the 12 year period from 1992 to 2004, research carried out to assess the scope of acupuncture to reduce pain and improve function in knee OA has indicated that patients being treated with acupuncture as an adjunctive therapy improve significantly when compared to control groups, and improve more than similar groups receiving sham acupuncture.

5.1 Strengths of the Reviewed Research

- The reviewed research has been carried out by professionals appropriately qualified in their field culminating in the largest study (Berman et al 2004) led by Brian Berman, M.D., Director of the Centre for Integrated Medicine and Professor of Family Medicine at the University of Maryland School of Medicine, Baltimore, Maryland USA.
- Acupuncture is a known beneficial treatment for knee OA, but is not currently considered as a treatment modality in orthodox medicine – the existing body of research seeks to measure the benefits of acupuncture by subjecting acupuncture to the rigours of a western medical trial. Whilst this may compromise the treatment, it allows acupuncture to be tested and scientifically proven.
- The progression of research builds on earlier findings, with improvements developing through the process of critical analysis and evaluation. This progression includes trials developing to include randomisation, sham acupuncture, addressing the placebo effect

and blinding of participants and evaluators. Numbers of participants in trials also increased, culminating in the Berman et al (2004) study of 570 patients.

- No significant adverse reactions are reported and no participants had a worsening in their knee OA. This contrasts well with drug therapy where adverse effects are well documented.
- The available research includes work contrasting acupuncture as an alternative and as an adjunctive therapy.
- Although research can be criticised, the results consistently show statistically significant improvements in patients treated with acupuncture.

5.2 Weaknesses of the Reviewed Research

In terms of Traditional Acupuncture, the research conducted in the west has reduced acupuncture to needling only. Diagnostic tools such as pulse and tongue diagnosis are not incorporated, and no diagnosis is made of the type of *Bi-syndrome* suffered. Traditional acupuncture treatments such as *moxabustion* and *cupping* are not considered. Treatment in these trials is standardised for all recipients (with the exception of Witt et al 2004), focusing solely on the knee and not on other concurrent health issues, weakening the total potential benefit available to patients.

- Methodological weaknesses include difficulties incorporating and administering sham acupuncture, difficulties blinding patients and the impossibility of blinding practitioners. Kaptchuk (2001) suggests teaching subjects to use acupressure on points

as a method of blinding practitioners, but this weakens the effects of treatment and therefore compromises results. Double blind trials seem elusive.

- The placebo effect may be considered a weakness in all of the trials with the possible exception of Witt (2004). Frank (2001) notes that a legitimate conclusion of acupuncture trials may be that a more intensive placebo is more effective than a less intensive placebo. Those receiving real acupuncture have, potentially, a more complex interaction than those receiving sham acupuncture. Add to this the difficulties of blinding practitioners and patient awareness of which procedure (real or sham) is being administered.
- There is some variation in points used between the individual papers. This may be a weakness when considering the entire body of research, but accurately mirrors the individual nature of acupuncture treatment. Vangermeersch et al (1994) suggest correct treatment of *Bi Syndrome* involves different therapeutic principles based on correct diagnosis of the predominant causative factor. No paper gave any source for the selection of points.
- Studies focus on acupuncture being standardised and intensively delivered which is not representative of a normal course of acupuncture treatment. Singh et al (1999) is the only paper to acknowledge this. The majority of patients are unlikely to be able to fund and attend intensive acupuncture treatment.
- Many studies were weakened by short durations of 12 weeks and under, although Berman et al (2004) treated and studied participants for 26 weeks and Witt (2004) followed up for 52 weeks.

5.3 Consolidation

The problems faced by acupuncture, as it moves towards integration with orthodox medicine, are that it comes from a base of empirical evidence and (as noted by Williams 1996) is based on philosophies and principles dramatically different from those of the West.

Acupuncture would seem to offer knee OA sufferers an alternative when unable or unwilling to rely on medication, or be considered as candidates for surgery. Acupuncture also works as an adjunctive therapy, offering potential for patients to reduce medication, and extend the time before surgery becomes essential through a reduction in pain and increase in function. These benefits can be achieved without side effects. In addition, Traditional Acupuncture considers the whole patient, addressing other issues and increasing overall wellbeing.

The difficulty faced is that, in order for acupuncture to integrate and be accepted by orthodox medicine, it needs to be tested and scientifically proven. Case studies or qualitative methodologies might be better suited; however orthodox medicine considers controlled randomised double blind trials the 'gold standard'. Achieving double blinding (of both patient and practitioner) has proved elusive, resulting in, as observed by Vickers, (1995) specific effects being difficult to ascribe to treatment given thereby weakening what appears to be a significant and positive body of research.

Applying a logical western approach to a system based on defining data through the inductive and synthetic mode of cognition (Porket, cited in Jarret, 2003, pg 739) makes Traditional Acupuncture appear to be less effective than it might if an inductive approach to research were pursued instead. Hart (1998) sees the inductive approach as researchers gathering data, classifying and categorising it, before searching for patterns and potential theories. Qualitative research – for example action research or case studies – might allow researchers to collect facts,

study the relationship between them and facilitate the emergence of theories, in contrast to statistical analysis.

It is interesting to consider why there is such interest in researching acupuncture for knee OA. Marcus (2002) notes that during the last decade there has been an increase in both the popularity of alternative medicine and evidenced based medicine in clinical practice. These two developments are divergent, leading to increasingly opposing views between those who believe alternative medicines should be integrated into orthodox medicine based on their traditional use, and those who believe their safety and efficacy should be evaluated by randomised controlled trials.

There is little benefit in such research to the Traditional Acupuncturist, who uses pulse and tongue diagnosis, and sensory acuity, to diagnose either a pattern of disharmony, or a weakness in *CF* and evaluates the physical and mental state of the individual patient presenting with knee OA in order to treat the patient not the disease using a tailored selection of acupuncture points with appropriate needle technique, *moxabustion*, *cupping* and lifestyle advice. This contrasts with the approach taken by a busy GP who (in a consultation likely to last just a few minutes) can offer only pain relief to mask the condition and suggest that the patient returns when they have deteriorated sufficiently to warrant an increase in medication, additional medication such as sleeping tablets or referral to a consultant and consideration for surgery. Could these patients be made aware of the potential of acupuncture?

The body of research reviewed is aimed at presenting the benefits of needling only in the treatment of *Bi-Syndrome*, and excludes much of the treatment protocol that makes Traditional Acupuncture effective and prescriptive. However, it must be assumed that orthodox medicine is preparing to consider some aspects of acupuncture as an adjunctive therapy for knee OA patients based on the potential to benefit patients and save budgets without risk of adverse side effects. In the interim period, some patients will continue to self refer to acupuncturists when

faced with knee OA and orthodox medical practitioners can be better informed about the potential benefits for those who seek relief and hope through the growing body of critical reviews.

6. Recommendations

In the past 15 years, research has taken place into acupuncture and knee OA. which can serve as a basis for recommendations aimed towards making acupuncture treatment solid and reliable. It also illuminates areas where new research can extend and enhance the existing body of knowledge.

6.1 Common Findings

When acupuncture is studied for the treatment of knee OA solely there are common findings from all the major studies which encompass:

- Decreased pain (commonly by 40%) by 8 weeks
- Improved function by 8 weeks
- No significant adverse effects
- Acupuncture can be considered as a adjunct to western treatment

6.2 Individual Findings

Individual papers also contribute knowledge which includes:

- Patients receiving acupuncture may reduce analgesic consumption (Christensen et al 1992, Aiping 2001 and Vas et al 2004)
- Acupuncture works as effectively when used unilaterally (Tillu et al 2001)
- Acupuncture may be more effective in the treatment of medial knee pain rather than general knee pain (Creamer et al 1999)

- Acupuncture delivers a stronger response when used as an adjunctive therapy (Jubb 2004)
- Acupuncture may be more effective in treatment of early diagnosed knee OA (Creamer et al 1999 and Aiping 2001)
- Acupuncture may be more effective in treating pain than in improving function (Creamer et al 1999 and Ezzo et al 2000)
- Acupuncture and analgesic medication may be more effective than analgesic medication alone (Vas et al 2004)
- Benefits of acupuncture decline when treatment ceases (Singh et al 1999 and Witt et al 2004)

From these results, the recommendation to the GP who may diagnose knee OA in its early stages might be to inform patients that regular acupuncture treatment may be beneficial to reduce pain and improve function in an affected knee, without risk of significant side effects and can be undertaken in conjunction with a course of analgesic medication or used to achieve a reduction in medication consumption.

6.3 Recommendations for Future Research

Existing research also highlights potential benefits and suggests further research is worthwhile.

The areas in which research can develop the existing findings include:

- Studying Traditional Acupuncture treatment when practiced to its fullest potential and assessing not only improvements in knee OA but changes in overall patient wellbeing using qualitative or case study methodologies. Comparing and contrasting results from different styles of Traditional Acupuncture

- Studying Traditional Acupuncture in a setting, style, and frequency likely to replicate treatment as it is delivered to patients by a Traditional Acupuncturist using case study methodology
- Studying the action of acupuncture on early diagnosed knee OA
- Studying the action of acupuncture on patients who cannot tolerate analgesic medication and for whom surgery is not an option
- Developing a credible retractable sham acupuncture needle for use in future double blind trials

7. Conclusion

Traditional Acupuncture is practiced in a number of differing styles, with practitioners regarding patients as individual cases commonly resulting in a non standard treatment protocol. Practitioners may not always agree about a patient's *CF* or syndrome diagnosis however treatment aims to bring the whole person into a state of balance that facilitates healing. Developed from thousands of years of observational medicine, the emphasis is on remaining or becoming well. Side effects are minimal.

Western medicine divides the body into component parts and focuses on predicting causes and effects and standardising treatment protocols. It focuses on intervention rather than prevention and treatments are proven to work through rigorous scientific testing, however Beinfield et al (1991) notes some of the negative side effects of western medicine are indirect and delayed. No-one can doubt the miraculous benefits of knee replacement surgery, but whilst deteriorating to the point where this intervention is warranted, pain relief is the main treatment available from western medicine with, as noted by McTaggart (1996), well documented negative side effects.

By reviewing research into acupuncture as a treatment or adjunctive treatment for knee OA, it seems clear that potential exists, albeit incorporating a potentially significant placebo effect. There is a remarkable consensus amongst the researchers over a 14 year period, with papers consistently recording improvements in pain reduction and knee function. What is difficult to assess is the total benefit a patient might receive from Traditional Acupuncture as it is practiced in the UK today. Styles and approaches vary, and practitioners utilise a range of diagnostic and therapeutic techniques that were excluded from the research studies. The intensity of treatment is also likely to vary, making the outcome for an individual patient very hard to predict.

However it is apparent that there is sufficient evidence available for sufferers of knee OA with the time and funds available for private treatment to consider acupuncture as an alternative or adjunctive therapy early after diagnosis, safe in the knowledge that there are few and minor potential side effects and that benefits may be a significant reduction in pain and increase in function.

Further research is also worthwhile to inform practice and make acupuncture treatment reliable.

Evaluation of the Research Process

A SWOT analysis can provide a useful model to evaluate the process of researching and producing this dissertation from the author's perspective. Strengths and Weakness highlight internal factors, Opportunities and Threats external factors.

Strengths		Weaknesses	
1	Ability to source literature.	1	Managing time restraints.
2	Development of critical awareness.	2	Lack of information to inform Five Element practice.
3	Overview of acupuncture styles and western diagnosis and treatments.	3	Research flaws frustrate progression of knowledge.
4	Ability to develop recommendations based on critically reviewing literature.	4	Divergence of subject and research style.
5		5	Volume of central literature difficult to review within limits of project word count.
Opportunities		Threats	
1	Interaction with western healthcare.	1	Justification of acupuncture to western healthcare.
2	Development of academic style through mentoring.	2	Balancing demands of academic work with acupuncture practice.
3	Publishing work that may inform future practice.	3	Only literature in English could be accommodated in this study.

Evidence of Personal and Professional Development

The process of researching a subject and distilling information for presentation in a dissertation was demanding but ultimately resulted in the development of new skills and knowledge.

Firstly I became aware that researching the subject is the most time consuming part. Information from all over the world is now available on the internet. The process of gathering it together, reading and critically evaluating it in order to identify the most valid was far more demanding and time consuming than I had anticipated, and accounted for many months of work.

My ability to critically evaluate research papers has progressed, particularly recognising that papers may present their findings to suit their aims. It was fascinating to learn more about the placebo effect and its role in acupuncture treatment. The research module of our degree had not previously captured my imagination, but this project showed me the practical application of the teaching received. The knowledge given empowered me to critically review the work of highly qualified experts.

As a student of Five Element Acupuncture, it was interesting to gain some insight into TCM and Western Medical Acupuncture practice and an appreciation of their own virtues and limitations. It was disappointing that Five Element Acupuncture has not been researched and therefore could not be reviewed. Acupuncture is often dismissed by western society as being 'unproven' and therefore invalid. I now feel better equipped to address this perspective through my understanding of the inductive and deductive processes, appropriateness of qualitative and quantitative research to eastern and western medicine and the difficulties of applying rigorous western medical trial methodologies to Traditional Acupuncture.

Undertaking a larger work than previously attempted has shown me that I am capable of sustained study, can make contact with experts for support and advice and achieve a level of expertise in a defined subject.

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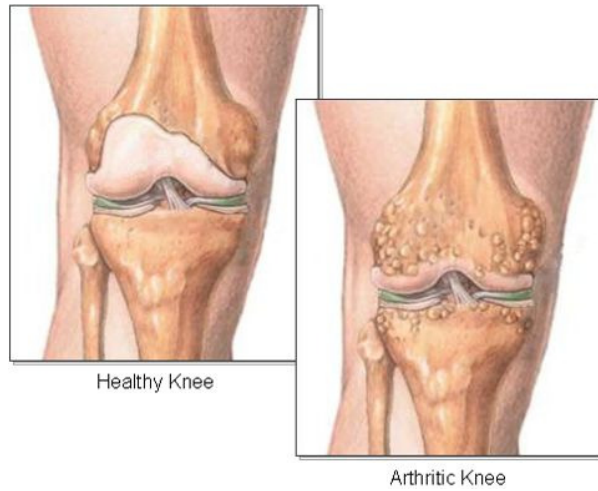
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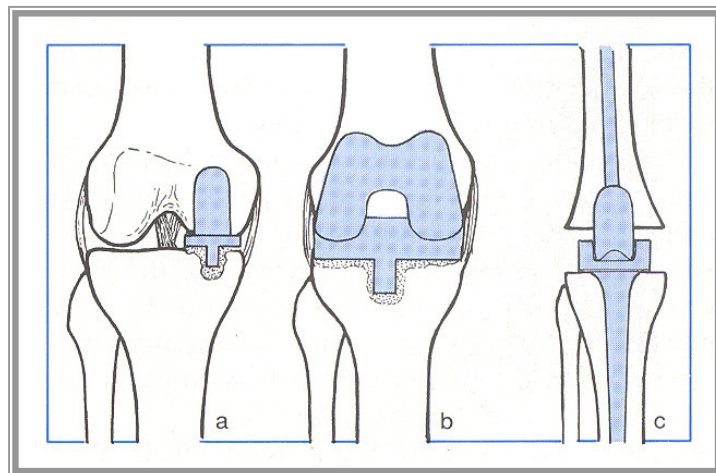
Appendix 1

Clinical Features of Knee OA

Knee OA can follow trauma, infection, meniscectomy, ligament injury or any insult to the joint.



The diagram below shows types of total knee replacement: (a) uni-compartmental arthroplasty; (b) unconstrained total knee replacement; (c) constrained hinge total knee replacement.



Dandy (1998) page 394

Appendix 2

Yin Yang Theory

Chinese medicine is based on the theory of two polar opposites, *Yin* and *Yang* which are the transitory manifestations of the *Dao*. *Yin*, in terms of health, is cold, wet, sinking, contracting, withdrawn etc, while *Yang* is hot, dry, rising, expanding, manic etc.

The relationship of *Yin* and *Yang* may be summarised as

- *Opposition – nothing is totally Yin or totally Yang, everything contains the seed of the opposite which forms a complementary union.*
- *Interdependence – One cannot exist in isolation. Hence contraction follows expansion, heat can collapse into cold etc.*
- *Mutual consumption – their relationship is dynamic and constantly changing, hence a patient may have an excess of Yin, or Yang, or a deficiency of Yin or Yang,*
- *Inter-transformation – Yin can change into Yang and vice versa.*

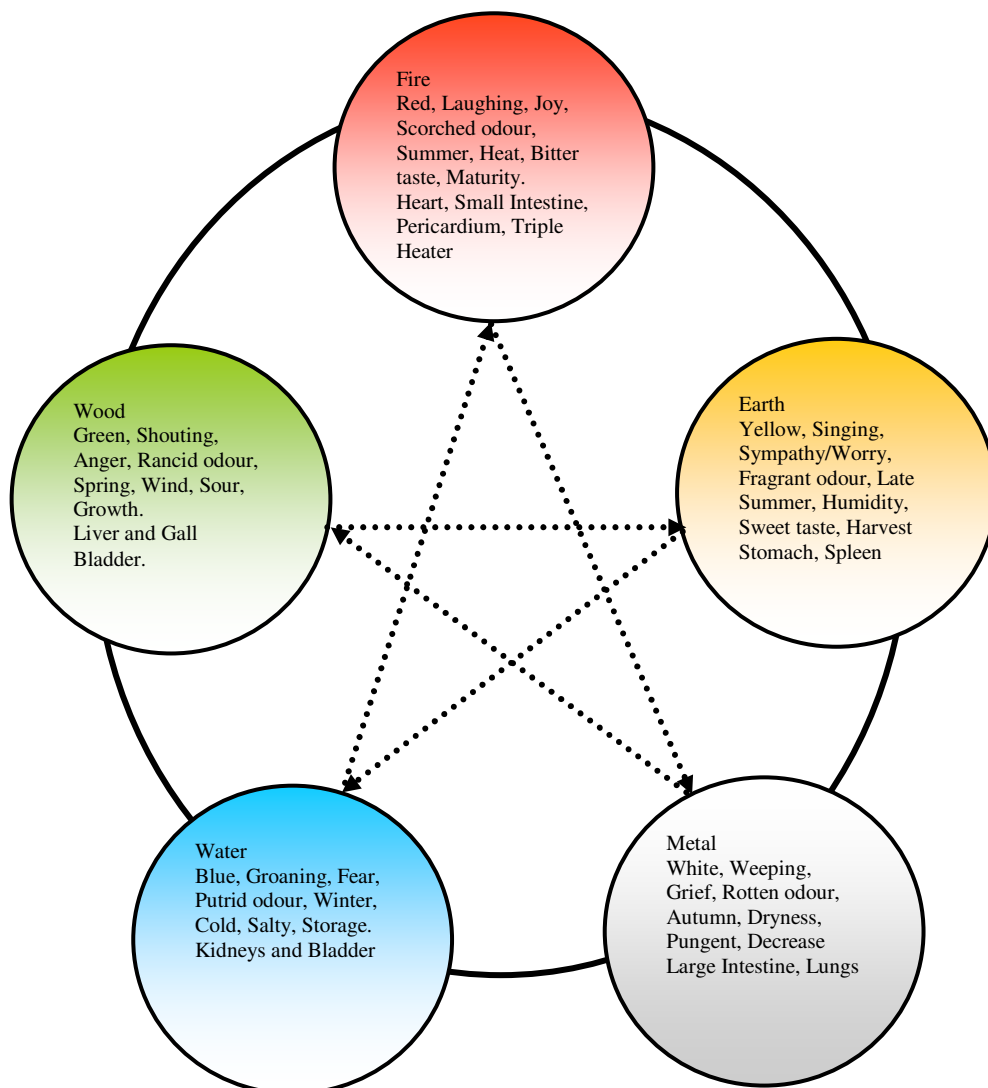
Traditional acupuncture has a fundamental aim of bringing the patient into a state of balance. In terms of knee OA, manifestations could be Yin in nature with a gradual onset, chronic profile, leading to coldness, a pale tongue and empty pulses.

Appendix 3

Five Element Models

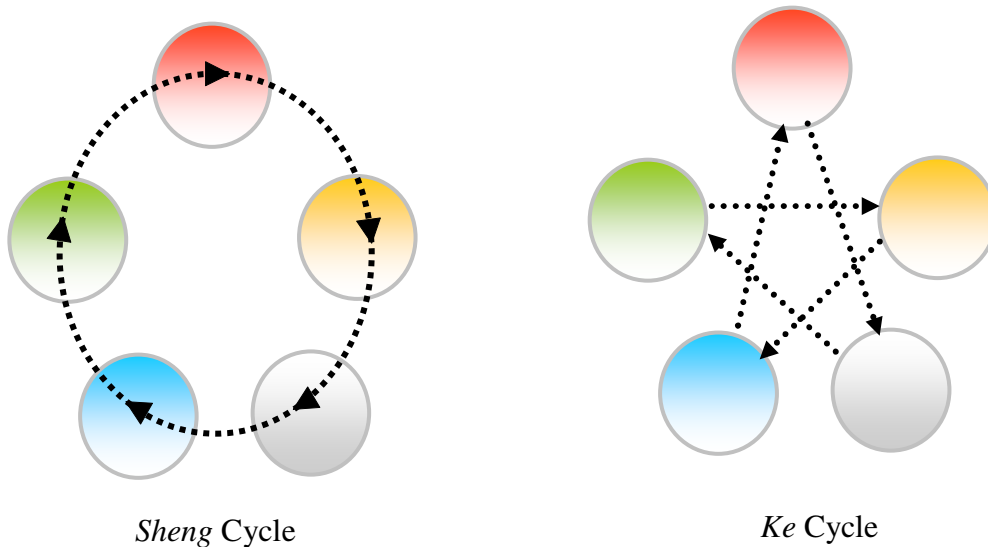
The Five Element model is set out in the Nei Jing and Nan Jing and shows the succession of seasons, with their individual resonances, can also govern behaviour in humans. Worsley (1923-2003) harnessed this model to understand and alleviate physical and psychological imbalances. His goal was to correctly assign a *CF* to each patient that would illuminate their weaknesses, which could be tonified or dispersed to bring about balance and health.

The Five Elements comprise Wood, Fire, Earth, Metal and Water. Each has a particular quality. When *Qi* becomes deficient or full, changes occur in the body, mind or spirit (or in a



combination). Diagnosis of the *CF* comes from the sensory acuity of the practitioner who is able to note disharmony in the patients colour, sound, odour and emotion.

Interrelationships exist between the Elements that can further assist diagnosis and treatment. Any *Element* can suffer from the imbalances of another Element through their connection on the *Sheng* and *Ke* Cycles.



Fundamental to Five Element acupuncture is the concept that the practitioner can effect change in the organs of an Element by treating another Element, based on the flow of energy through the *Sheng* Cycle, often known as the Mother-Child relationship.

The *Ke* cycle is concerned with control and is a more complex model of interrelationships. An Element out of balance can ‘insult’ the next Element on the *Ke* cycle rather than controlling it.

The skill of Five Element acupuncturists lies in their ability to discern which Element was the first to be unbalanced, and to effect a change in the patient through treatment of *Qi* at the root cause.

Other models are also important, including the concept of each organ Official having a 2 hour period each day when its *Qi* is strongest and weakest, and organ *Officials* are associated with functions beyond their physiological roles.

The Five Element model seeks to link nature and the external environment with changes taking place within the patient. The cycles and flows explain the movement of *Qi* through the *meridian* network.

Appendix 4

Symptomatic Treatments for Knee OA

Eyes of the Knee

Vangermeersch (1994) advocates using this 3 needle technique as part of a TCM treatment protocol for *Bi-syndrome*, but it has also been adopted by Five-Element acupuncture as a symptomatic treatment for the knee in cases of knee OA. The table below is taken from 3 sources: Point combinations are taken from Vangermeersch (1994), locations are from Lian (2005) and indications from Deadman (1998).

Point	Location	Indication
Extra Point M-LE-27 (<i>He Ding</i>)	In the depression at the midpoint of the superior border of the patella.	This point is combined with St34 and MN-LE 16 to treat any arthritic pain with or without swelling of the knee joint.
Stomach 35 (St35)	In the depression on lower edge of patella, lateral to patella ligament.	Dispels wind, cold, dampness and heat. Activates circulation in the meridian, sedates pain, numbness and stiffness in the knee and aids its smooth function.
Extra Point MN-LE-16 Medial (<i>Xi Yan</i>)	On the knee, in the hollow formed when the knee is flexed immediately below the patella.	Expels Wind Damp Cold and Heat ,improves circulation in the meridians and benefits the knee.

If cold is diagnosed, burning moxa on these points prior to needling will benefit the patient.

Bachmann's Knee Points

Bachmann was a German acupuncturist who developed this treatment in the 1960's to benefit pain and stiffness in the knee. The College of Traditional Acupuncture (1998) advocates the treatment only after establishing and treating the *CF*, as an adjunct to Five Element treatments.

Five points are needled, four arranged at the edge of the patella at 12, 3, 6 and 9 o' clock positions, and one needle in the central notch of the patella. *Moxa* (up to 5 cones) may be burnt on each point to warm a cold joint, and needle technique can be tonification or dispersal depending on the diagnosis.

This treatment is not suitable for a hot and swollen knee as it has the potential to aggravate.

The treatment can be used in conjunction with *A-Shi* points and Eyes of the Knee points.

Appendix 5

Point Selection for the Treatment of *Bi-Syndrome* of the knee joint

A-shi points

These are points which are tender on palpation and often not corresponding to known acupuncture points. Needling of these points may be very helpful in joint pain, according to Vangermeersch (1994)

Bi Syndrome arising from the knee joint

The tables below are taken from 3 sources: Point combinations are taken from Vangermeersch (1994), locations are taken from Lian (2005) and indications are taken from Deadman (1998).

Only those indications that are of interest to knee symptoms have been included and it is worth noting that these points are also useful for a range of other conditions.

Cun measurements are used to divide up sections of the body into equal parts.

Point combination 1

Point	Location	Indication
Stomach 34 (St34)	With a flexed knee, on the connecting line between the anterior superior iliac spine and superior lateral corner of patella, 2 cun proximal.	Swelling and pain in knee joint, expels wind-cold-damp, clears heat. Alleviates numbness and stiffness in knee and surrounding tissue.
Spleen 10 (Sp10)	2 cun proximal to medial superior border of patella on the bulge of the vastus medialis muscle.	Pain in inner aspect of thigh. Regulates Blood by nourishing it and reducing stasis.
Liver 8 (Liv 8)	At the medial end of the popliteal crease, dorsal to the medial condyle of the tibia in the depression at the anterior border of the onset of the semi-membranosus and semi-tendinosus muscles.	Eliminates dampness, relaxes muscles and tendons, and circulates <i>Qi</i> and <i>Blood</i> in the channels. Strengthens the knee.

Point	Location	Indication
Stomach 35 (St35)	In the depression on lower edge of patella, lateral to patella ligament.	Dispels wind, cold, dampness and heat. Activates circulation in the meridian, sedates pain, numbness and stiffness in the knee and aids its smooth function.

Point combination 2

Point	Location	Indication
Gallbladder 34 (Gb34)	In the depression ventral and distal to the head of the fibula.	Influences tendons by relaxing and strengthening them. Clears heat and dampness.
Spleen 9 (Sp9)	In the depression distal and dorsal to the medial condyle of the tibia.	Resolves dampness, unblocks the meridian and has a local effect on pain and swelling in the knee. Regulates Blood by nourishing it and reducing stasis.
Stomach 35 (St35)	In the depression on lower edge of patella, lateral to patella ligament.	Dispels wind, cold, dampness and heat. Activates circulation in the meridian, sedates pain, numbness and stiffness in the knee and aids its smooth function.

Appendix 6

Point Combinations, Location and Indications (both TCM and Five Element) from Individual Research Trials

Point locations are taken from Lian (2005) and Deadman (1998). TCM indications are taken from Deadman (1998) and Vangermeersch (1994), Five Element indications are taken from CTA Compendium (2004). Only those indications that are of interest to knee symptoms have been included and it is worth noting that these points also treat a range of other conditions.

For the purpose of this work, a basic guide to a *cun* measurement may be taken as the width of the thumb at the interphalangeal joint.

The *meridians* that run through the knee are Stomach, Spleen, Gallbladder, Liver, Bladder and Kidney.

4.3.4 Berman et al (1999)

Point	Location	TCM Indication	Five Element Indication
Gall Bladder 34 (Gb34)	In the depression ventral and distal to the head of the fibula.	Cold, painful obstruction of the knee Disorders of the sinews, contraction and pain in the calf muscles, stiffness and tightness of muscles and joints.	Tonifying effect on sinews, moves stagnation in the meridian, Strengthens weak muscles and relaxes spasm from stagnation. Promotes circulation of <i>Qi</i> and <i>Blood</i> to the legs. Local point for the knee.
Spleen 9 (Sp 9)	In the depression distal and dorsal to the medial condyle of the tibia.	Resolves swelling of the knee and painful obstruction on the leg.	Eliminates Damp <i>Bi</i> of the knee.

Point	Location	TCM Indication	Five Element Indication
Stomach 36 (St 36)	3 cun inferior to St35, one middle fingerbreadth lateral to the anterior crest of the tibia at the level of the distal edge of the tuberosity of the tibia.	Resolves Dampness, tonifies <i>Qi</i> and nourishes <i>Blood</i> . Activates the <i>Meridian</i> and relieves pain.	Local point for the knee. Expels Wind and Damp, reduces pain and activates the Meridian. Nourishes the sinews. Assists weakness and chronic ill health.
Stomach 35 (St 35) Xi yan – one of the ‘eyes of the knee’	In the depression on the lower edge of the patella, lateral to the patella ligament, when the knee is flexed.	Reduces swelling and pain in the knee, improves flexion and extension in the knee, strengthens the knee and reduces numbness. Dispels Wind/Damp and reduces swelling. Activates the meridian and alleviates pain.	Relieves painful and swollen knees. Expels Damp and Cold with moxa. When combined with medial <i>Xi Yan</i> known as Eyes of the Knee.
Extra Point MN-LE-16 (<i>Xi Yan</i>) One of the ‘eyes of the knee’	On the knee, in the hollow formed when the knee is flexed immediately below the patella.	Expels Wind Damp Cold and Heat, improves circulation in the meridians and benefits the knee.	
Bladder 60 (Bl60) Contra indicated in pregnancy – promotes labour.	At the midpoint between the prominence of the lateral malleolus and tendocalcaneus.	Clears Heat. Alleviates pain, relaxes sinews.	Clears Heat, expels Wind. Activates and removes obstructions from the meridian, eases pain.
Gallbladder 39 (Gb39)	3 cun proximal to the prominence of the lateral malleolus on the anterior border of the fibula.	Stiffness and pain, chronic painful obstruction, injury by cold pathogen leading to contracted sinews and pain in the bones, numbness and pain in the knee and lower leg, sciatica.	Alleviates pain in the <i>meridian</i> , distal point to benefit bones and sinews, pain and soreness of the lower leg, benefits joint stiffness, muscle weakness and inflammation. Used for severe arthritis.
Spleen 6 (Sp 6)	3 cun proximal to the prominence of the medial malleolus, dorsal to the crest of the tibia.	Leg pain, damp painful obstruction in lower limbs.	Affects the 3 <i>Yin meridians</i> of the leg, clears damp
Kidney 3 (Ki 3)	In the depression between the prominence of the medial malleolus and tendocalcaneus.	Injury by cold, numbness and pain in the legs.	Warms cold, strengthens bones.

4.3.6 Tillu et al (2001)

4.3.7 Tillu et al (2002)

Point	Location	TCM Indication	Five Element Indication
Spleen 9 (Sp 9)	In the depression distal and dorsal to the medial condyle of the tibia.	Resolves swelling of the knee and painful obstruction on the leg.	Eliminates Damp <i>Bi</i> of the knee.
Stomach 36 (St 36)	3 cun inferior to St35, one middle fingerbreadth lateral to the anterior crest of the tibia at the level of the distal edge of the tuberosity of the tibia	Resolves Dampness, tonifies <i>Qi</i> and nourishes <i>Blood</i> . Activates the <i>Meridian</i> and relieves pain.	Local point for the knee. Expels Wind and Damp, reduces pain and activates the Meridian. Nourishes the sinews. Assists weakness and chronic ill health.
Spleen 10 (Sp10)	2 cun proximal to the medial superior border of the patella on the bulge of the vastus medialis muscle	Invigorates Blood and dispels stasis.	Moves Blood in the leg and knee.
Stomach 34 (St 34)	On the connecting line between the anterior superior iliac spine and the superior lateral corner of the patella, 2 cun proximal when the knee is flexed.	Moderates acute conditions, swelling and pain in the knee, difficulties with flexion and extension in the knee, cold painful obstruction with numbness and difficulties in walking.	Removes obstruction in the meridian. Clears heat.
Large Intestine 4 (LI 4) Contra indicated in pregnancy – promotes labour	On the dorsum of the hand, to the side of the midpoint on the second metacarpal, in the abductor pollicis muscle.	Used in painful obstruction of the four limbs and in the sinews and bones.	Clears Wind and Heat.

4.3.8 Aiping et al (2001)

Point	Location	TCM Indication	Five Element Indication
Stomach 36 (St 36)	3 cun inferior to St35, one middle fingerbreadth lateral to the anterior crest of the tibia at the level of the distal edge of the tuberosity of the tibia.	Resolves Dampness, tonifies <i>Qi</i> and nourishes <i>Blood</i> . Activates the <i>Meridian</i> and relieves pain.	Local point for the knee. Expels Wind and Damp, reduces pain and activates the Meridian. Nourishes the sinews. Assists weakness and chronic ill health.
Spleen 10 (Sp10)	2 cun proximal to the medial superior border of the patella on the bulge of the vastus medialis muscle.	Invigorates Blood and dispels stasis.	Moves Blood in the leg and knee.
Stomach 34 (St 34)	On the connecting line between the anterior superior iliac spine and the superior lateral corner of the patella, 2 cun proximal when the knee is flexed.	Moderates acute conditions, swelling and pain in the knee, difficulties with flexion and extension in the knee, cold painful obstruction with numbness and difficulties in walking.	Removes obstruction in the meridian. Clears heat.
EX-LE 4 Inner Eye of the Knee	In the depression medial to the patella ligament opposite St 35.	Relaxes the tendons, alleviates pain in the knee joint.	
EX-LE 5 Eyes of the Knee	Two points, medial and lateral to the patella ligament (The lateral point corresponds to St 35).	Relaxes the tendons, alleviates pain in the knee joint.	

4.3.10 Witt et al (2003)

Point	Location	TCM Indication	Five Element Indication
Spleen 9 (Sp 9)	In the depression distal and dorsal to the medial condyle of the tibia.	Resolves swelling of the knee and painful obstruction on the leg.	Eliminates Damp <i>Bi</i> of the knee.
Stomach 36 (St 36)	3 cun inferior to St35, one middle fingerbreadth lateral to the anterior crest of the tibia at the level of the distal edge of the tuberosity of the tibia.	Resolves Dampness, tonifies <i>Qi</i> and nourishes <i>Blood</i> . Activates the <i>Meridian</i> and relieves pain.	Local point for the knee. Expels Wind and Damp, reduces pain and activates the Meridian. Nourishes the sinews. Assists weakness and chronic ill health.
Spleen 10 (Sp10)	2 cun proximal to the medial superior border of the patella on the bulge of the vastus medialis muscle.	Invigorates Blood and dispels stasis.	Moves Blood in the leg and knee.
Stomach 34 (St 34)	On the connecting line between the anterior superior iliac spine and the superior lateral corner of the patella, 2 cun proximal when the knee is flexed.	Moderates acute conditions, swelling and pain in the knee, difficulties with flexion and extension in the knee, cold painful obstruction with numbness and difficulties in walking.	Removes obstruction in the meridian. Clears heat.
Extra Point M-LE-27 (<i>He Ding</i>)	In the depression at the midpoint of the superior border of the patella.	This point is combined with St34 and MN-LE 16 to treat any arthritic pain with or without swelling of the knee joint.	
Stomach 35 (St35) One of the 'Eyes of the Knee'	In the depression on lower edge of patella, lateral to patella ligament.	Dispels wind, cold, dampness and heat. Activates circulation in the meridian, sedates pain, numbness and stiffness in the knee and aids its smooth function.	Relieves painful and swollen knees. Expels Damp and Cold with moxa. When combined with medial <i>Xi Yan</i> known as Eyes of the Knee
Extra Point MN-LE-16 Medial (<i>Xi Yan</i>)	On the knee, in the hollow formed when the knee is flexed immediately below the patella.	Expels Wind Damp Cold and Heat ,improves circulation in the meridians and benefits the knee.	

Point	Location	TCM Indication	Five Element Indication
Bladder 40 (Bl 40)	In the middle of the popliteal crease.	Pain and stiffness in the knee.	Relaxes sinews, removes obstruction from the <i>meridian</i> , local point for the knee.
Kidney 10 (Ki 10)	In the medial part of the popliteal crease between tendons of the semi-teninosus and semi-membranosus.	Indicated for 'drilling' pain of the knee with immobility.	Reduces pain and weakness of the knees. Expels Damp.
Gallbladder 33 (Gb 33)	3 cun proximal to Gb 34, in the depression proximal to the lateral epicondyle of the femur.	Relaxes the sinews, benefits the joints, dispels Wind-damp. Indicated for swelling and pain of the lateral aspect of the knee.	Assists immobility of the knee with pain. Trauma to the knee, lower leg pain or numbness.
Gallbladder 34 (Gb 34)	In the depression ventral and distal to the head of the fibula.	Contraction of the sinews, painful obstruction of the lower leg, swelling and pain in the knee with redness. Activates the <i>meridian</i> and alleviates pain.	Contraction and spasm of the sinews, removes obstructions from the channel, aids stiffness and weakness of the knee and treats <i>Bi</i> of the knee.
Liver 8 (Liv 8)	At the medial end of the popliteal crease, dorsal to the medial condyle of the tibia, in the depression at the anterior border of the onset of the tendons of the semi-teninosus and semi-membranosus.	Knee pain, swelling and pain in the patella, coldness and pain in the knee joint, extreme pain.	Nourishes sinews and strengthens the knee. Useful for <i>bi</i> symptoms in the medial compartment of the knee.
Spleen 4 (Sp 4)	In the depression distal and inferior to the base of the first metatarsal bone, at the change in skin colour.	Regulates Qi and resolves Damp.	Benefits the medial aspect of the leg. Helps circulation in the legs.
Spleen 5 (Sp 5)	In the depression ventral and distal to the medial malleolus, in the middle between the tuberosity of the navicular and the prominence of the medial malleolus.	Resolves Damp. Benefits sinews and bones.	Local point for knee problems, resolves damp in <i>Bi Syndrome</i> .

Point	Location	TCM Indication	Five Element Indication
Spleen 6 (Sp 6)	3 cun proximal to the prominence of the medial malleolus, dorsal to the medial crest of the tibia.	Resolves dampness, invigorates Blood, activates the channel and alleviates pain.	Supports the 3 <i>Yin meridians</i> of the leg. Resolves Damp.
Bladder 20 (Bl 20)	At the level of the depression inferior to T11, 1.5 cun lateral to the dorsal midline.	Resolves dampness.	Indicated for chronic illness where Spleen is deficient. Regulates damp.
Bladder 57 (Bl 57)	At the tip of the depression formed between the twin bellies of the gastrocnemius.	Cramps and pain from contracted sinews, tonifies leg <i>Qi</i> where there is weakness and heaviness in the leg.	Relaxes sinews, removes obstruction from the <i>meridian</i> , and relieves pain, benefits lower leg.
Bladder 58 (Bl 58)	7 cun proximal to Bl 60, 1 cun lateral and distal to Bl 57, between the gastrocnemius and soleus muscles.	Weakness of the legs, difficulties walking, coldness in the legs, painful Wind obstruction in the joints.	Removes obstructions from the <i>meridian</i> , expels Wind.
Bladder 60 (Bl 60) Caution in pregnancy	At the mid point between the prominence of the lateral malleolus and tendocalcaneous.	Alleviates pain, relaxes the sinews, reduces pain behind the knee.	Expels Wind and moves Blood.
Bladder 62 (Bl 62)	In the depression distal to the lateral malleolus.	Painful cold obstruction, difficulties with flexion and extension of the knee. Activates the <i>meridian</i> and alleviates pain.	Pain of the lower back and leg. Relaxes Sinews. Dispels Wind and Cold.
Kidney 3 (Ki 3)	In the depression between the prominence of the medial malleolus and tendocalcaneous.	Injury by cold, numbness and pain in the legs.	Warms cold, strengthens bones.

4.3.11 Vas et al (2004)

Point	Location	TCM Indication	Five Element Indication
Spleen 9 (Sp 9)	In the depression distal and dorsal to the medial condyle of the tibia.	Resolves swelling of the knee and painful obstruction on the leg.	Eliminates Damp <i>Bi</i> of the knee.
Stomach 36 (St 36)	3 cun inferior to St35, one middle fingerbreadth lateral to the anterior crest of the tibia at the level of the distal edge of the tuberosity of the tibia.	Resolves Dampness, tonifies <i>Qi</i> and nourishes <i>Blood</i> . Activates the <i>Meridian</i> and relieves pain.	Local point for the knee. Expels Wind and Damp, reduces pain and activates the Meridian. Nourishes the sinews. Assists weakness and chronic ill health.
Kidney 3 (Ki 3)	In the depression between the prominence of the medial malleolus and tendocalcaneous.	Injury by cold, numbness and pain in the legs.	Warms cold, strengthens bones.
EX-LE-5 Eyes of the Knee	Two points, medial and lateral to the patella ligament (The lateral point corresponds to St 35).	Relaxes the tendons, alleviates pain in the knee joint.	
Gallbladder 34 (Gb 34)	In the depression ventral and distal to the head of the fibula.	Contraction of the sinews, painful obstruction of the lower leg, swelling and pain in the knee with redness. Activates the <i>meridian</i> and alleviates pain.	Contraction and spasm of the sinews, removes obstructions from the channel, aids stiffness and weakness of the knee and treats <i>Bi</i> of the knee.
Spleen 6 (Sp 6)	3 cun proximal to the prominence of the medial malleolus, dorsal to the medial crest of the tibia.	Resolves dampness, invigorates Blood, activates the channel and alleviates pain.	Supports the 3 <i>Yin meridians</i> of the leg. Resolves Damp.

4.3.12 Jubb (2004)

Point	Location	TCM Indication	Five Element Indication
Spleen 9 (Sp 9)	In the depression distal and dorsal to the medial condyle of the tibia.	Resolves swelling of the knee and painful obstruction on the leg.	Eliminates Damp <i>Bi</i> of the knee.
Stomach 36 (St 36)	3 cun inferior to St35, one middle fingerbreadth lateral to the anterior crest of the tibia at the level of the distal edge of the tuberosity of the tibia.	Resolves Dampness, tonifies <i>Qi</i> and nourishes <i>Blood</i> . Activates the <i>Meridian</i> and relieves pain.	Local point for the knee. Expels Wind and Damp, reduces pain and activates the <i>Meridian</i> . Nourishes the sinews. Assists weakness and chronic ill health.
Spleen 10 (Sp10)	2 cun proximal to the medial superior border of the patella on the bulge of the vastus medialis muscle.	Invigorates Blood and dispels stasis.	Moves Blood in the leg and knee.
Extra Point MN-LE-16 Medial (<i>Xi Yan</i>)	On the knee, in the hollow formed when the knee is flexed immediately below the patella.	Expels Wind Damp Cold and Heat ,improves circulation in the meridians and benefits the knee.	
Bladder 40 (Bl 40)	In the middle of the popliteal crease.	Pain and stiffness in the knee.	Relaxes sinews, removes obstruction from the <i>meridian</i> , local point for the knee.
Gallbladder 34 (Gb 34)	In the depression ventral and distal to the head of the fibula.	Contraction of the sinews, painful obstruction of the lower leg, swelling and pain in the knee with redness. Activates the <i>meridian</i> and alleviates pain.	Contraction and spasm of the sinews, removes obstructions from the channel, aids stiffness and weakness of the knee and treats <i>Bi</i> of the knee.
Bladder 57 (Bl 57)	At the tip of the depression formed between the twin bellies of the gastrocnemius.	Cramps and pain from contracted sinews, tonifies leg <i>Qi</i> where there is weakness and heaviness in the leg.	Relaxes sinews, removes obstruction from the <i>meridian</i> , and relieves pain, benefits lower leg.
Large Intestine 4 (LI 4) Contra indicated in pregnancy – promotes labour	On the dorsum of the hand, to the side of the midpoint on the second metacarpal, in the abductor pollicis muscle.	Used in painful obstruction of the four limbs and in the sinews and bones.	Clears Wind and Heat.

Point	Location	TCM Indication	Five Element Indication
Liver 3 (Liv 3)	On the dorsum of the foot, in the depression distal to the proximal corner between the first and second metatarsal bones.	Pain and restricted movement in the lower extremity.	Expels wind, calms spasm and contraction, used in painful obstruction where Wind is the dominant factor.

4.3.13 Berman et al (2004)

Point	Location	TCM Indication	Five Element Indication
Spleen 9 (Sp 9)	In the depression distal and dorsal to the medial condyle of the tibia.	Resolves swelling of the knee and painful obstruction on the leg.	Eliminates Damp <i>Bi</i> of the knee.
Stomach 36 (St 36)	3 cun inferior to St35, one middle fingerbreadth lateral to the anterior crest of the tibia at the level of the distal edge of the tuberosity of the tibia.	Resolves Dampness, tonifies <i>Qi</i> and nourishes <i>Blood</i> . Activates the <i>Meridian</i> and relieves pain.	Local point for the knee. Expels Wind and Damp, reduces pain and activates the Meridian. Nourishes the sinews. Assists weakness and chronic ill health.
Stomach 35 (St35) One of the 'Eyes of the Knee'	In the depression on lower edge of patella, lateral to patella ligament.	Dispels wind, cold, dampness and heat. Activates circulation in the meridian, sedates pain, numbness and stiffness in the knee and aids its smooth function.	Relieves painful and swollen knees. Expels Damp and Cold with moxa. When combined with medial <i>Xi Yan</i> known as Eyes of the Knee.
Extra Point MN-LE-16 Medial (<i>Xi Yan</i>)	On the knee, in the hollow formed when the knee is flexed immediately below the patella.	Expels Wind Damp Cold and Heat ,improves circulation in the meridians and benefits the knee.	
Gallbladder 34 (Gb 34)	In the depression ventral and distal to the head of the fibula.	Contraction of the sinews, painful obstruction of the lower leg, swelling and pain in the knee with redness. Activates the <i>meridian</i> and alleviates pain.	Contraction and spasm of the sinews, removes obstructions from the channel, aids stiffness and weakness of the knee and treats <i>Bi</i> of the knee.
Spleen 6 (Sp 6)	3 cun proximal to the prominence of the medial malleolus, dorsal to the medial crest of the tibia.	Resolves dampness, invigorates Blood, activates the channel and alleviates pain.	Supports the 3 <i>Yin meridians</i> of the leg. Resolves Damp.
Bladder 60 (Bl 60) Caution in pregnancy	At the mid point between the prominence of the lateral malleolus and tendocalcaneous.	Alleviates pain, relaxes the sinews, reduces pain behind the knee.	Expels Wind and moves Blood.
Kidney 3 (Ki 3)	In the depression between the prominence of the medial malleolus and tendocalcaneous.	Injury by cold, numbness and pain in the legs.	Warms cold, strengthens bones.

Point	Location	TCM Indication	Five Element Indication
Gallbladder 39 (GB 39)	3 cun proximal to the maximum prominence of the lateral malleolus on the anterior border of the fibula.	Benefits sinews and bones, dispels Wind/Damp, activates the <i>meridian</i> and relieves pain.	Alleviates pain along the meridian, benefits sinews and bones, distal point for pain radiating down legs, eases joint stiffness.

Sources:

Location, Lian (2005)

TCM Indications. Deadman (1998)

Five Element Indication, CTA (2004)

Appendix 7

Characteristics of Included Studies

Study Identifier	Methods	Participants	Interventions	Outcomes
Christensen et al 1992	<p>Random allocation: Yes. Concealed allocation: No. Baseline comparability: Unclear. Blind assessors: Yes. Blind participants: No. Blind acupuncturists: Not possible. Adequate follow up: Unclear. Intention to treat analysis: No. Between group comparisons: Yes.</p>	<p>Number of participants: 29 Inclusion criteria: Knee OA patients awaiting arthroplasty surgery to one or both knees. Exclusion criteria: Unclear.</p>	<p>Group A: Acupuncture treatment to affected knees. Group B: No treatment control group for 9 weeks, followed by acupuncture treatment to affected knees.</p>	<p>1. Objective measurement of pain by blinded assessors. 2. Changes in analgesic consumption. 3. Objective measurement of knee range movement.</p>
Berman et al 1999	<p>Random allocation: Yes. Concealed allocation: No. Baseline comparability: Yes. Blind assessors: Yes. Blind participants: No. Blind acupuncturists: Not possible. Adequate follow up: Unclear. Intention to treat analysis: Yes. Between group comparisons: Yes.</p>	<p>Number of participants: 73 Inclusion criteria: Elderly patients with symptomatic knee OA. Exclusion criteria: Recent corticosteroid injection to knee, severe concomitant illness or history of uncontrollable bleeding.</p>	<p>Acupuncture Group: Acupuncture treatment for <i>Bi-Syndrome</i> for 8 weeks. Control Group: Continued with usual medication and received acupuncture after 8 weeks.</p>	<p>1. Patients self scored for pain, stiffness and physical function using the WOMAC and Lequesne scales.</p>
Tillu et al 2001	<p>Random allocation: Yes. Concealed allocation: No. Baseline comparability: Unclear. Blind assessors: Yes. Blind participants: No. Blind acupuncturists: Not possible. Adequate follow up: Unclear. Intention to treat analysis: No.</p>	<p>Number of participants: 44 Inclusion criteria: Patients with advanced knee OA awaiting total knee joint replacement.</p>	<p>Group A: Acupuncture to most affected knee only. Group B: Acupuncture to both knees.</p>	<p>1. Objective and subjective measurement using VAS and HSS score. 2. Ability to walk 50m and climb 20 steps.</p>

Study Identifier	Methods	Participants	Interventions	Outcomes
	between group comparisons: Yes.	Exclusion criteria: Acupuncture treatment in the past year, intra-articular steroid injection with three months and non-idiopathic arthritis.		
Tillu et al 2002	Random allocation: Unclear. Concealed allocation: No. Baseline comparability: Unclear. Blind assessors: No. Blind participants: No. Blind acupuncturists: Not possible. Adequate follow up: Unclear. Intention to treat analysis: No. Between group comparisons: Yes.	Number of participants: 75 Inclusion criteria: Consecutive patients on a waiting list for total knee replacement surgery. Exclusion criteria: arthroscopic washout within six months, intra-articular steroid injection within 3 months, acupuncture treatment within 1 year and inflammatory arthritis.	Group A: Acupuncture treatment for 6 weeks. Group B: No treatment control group.	1. Objective and subjective measurement using VAS and HSS score. 2. Ability to walk 50 m and climb 20 steps.
Aiping et al 2001	Random allocation: Unclear. Concealed allocation: No. Baseline comparability: Unclear. Blind assessors: No. Blind participants: No. Blind acupuncturists: Not possible. Adequate follow up: Unclear. Intention to treat analysis: No. Between group comparisons: Yes.	Number of participants: 109 Inclusion criteria: Radiological diagnosis of knee OA. Exclusion criteria: Unclear	All participants received acupuncture. Some received moxabustion or heat treatment and cupping according to diagnosis of <i>Bi-Syndrome</i> .	1. Patient's subjective ratings of pain relief and improvements in stiffness via three broad categories.
Witt et al 2003	Random allocation: Yes. Concealed allocation: Yes. Baseline comparability: Yes.	Number of participants: 300 Inclusion criteria: Chronic	Group A: Acupuncture treatment for 8 weeks.	1. Both acupuncture groups believed they had received true acupuncture.

Study Identifier	Methods	Participants	Interventions	Outcomes
	<p>Blind assessors: Yes.</p> <p>Blind participants: Yes.</p> <p>Blind acupuncturists: Not possible.</p> <p>Adequate follow up: Unclear.</p> <p>Intention to treat analysis: Yes.</p> <p>Between group comparisons: Yes.</p>	<p>knee OA (Kellgren grade 2 or more).</p> <p>Exclusion criteria: Inflammatory, malignant or autoimmune disease of the knee, knee surgery or arthroscopy within 1 year, chondroprotective or intra-articular injection in 4 months, beginning a new treatment for OA in 4 weeks, acupuncture in 1 year, physiotherapy in 4 weeks.</p>	<p>Group B: Minimal acupuncture to distal non acupuncture points.</p> <p>Group C: Control Group</p>	<p>2. Objective and subjective rating of pain and stiffness using WOMAC score.</p>
Vas et al 2004	<p>Random allocation: Yes.</p> <p>Concealed allocation: Yes.</p> <p>Baseline comparability: Unclear.</p> <p>Blind assessors: Yes.</p> <p>Blind participants: Unclear.</p> <p>Blind acupuncturists: Not possible.</p> <p>Adequate follow up: Unclear.</p> <p>Intention to treat analysis: Unclear.</p> <p>Between group comparisons: Yes.</p>	<p>Number of participants: 97</p> <p>Inclusion criteria: Patients with clinical and radiological diagnosis of knee OA taking diclofenac medication.</p> <p>Exclusion criteria: No previous experience of acupuncture, no concurrent serious medical conditions.</p>	<p>Group A: Acupuncture treatment and diclofenac.</p> <p>Group B: Sham acupuncture and diclofenac.</p>	<p>1. Objective and subjective rating of pain and stiffness using WOMAC score.</p> <p>2. Changes in analgesic intake.</p>
Jubb et al 2004	<p>Random allocation: Yes.</p> <p>Concealed allocation: No.</p> <p>Baseline comparability: Unclear.</p> <p>Blind assessors: Yes.</p> <p>Blind participants: No.</p> <p>Blind acupuncturists: Not possible.</p> <p>Adequate follow up: Unclear.</p>	<p>Number of participants: 30</p> <p>Inclusion criteria: Patients with knee OA (Kellgren scale 1 – 3) with clinical and radiological diagnosis.</p> <p>Previous non-response to in</p>	<p>Group A: Acupuncture treatment and cessation of analgesic medication.</p> <p>Group B: Acupuncture treatment and usual analgesic medication.</p>	<p>1. Objective and subjective rating of pain and stiffness using VAS and WOMAC scores.</p>

Study Identifier	Methods	Participants	Interventions	Outcomes
	<p>Intention to treat analysis: No. Between group comparisons: Yes.</p>	<p>and out patient treatment and no previous experience of acupuncture. Exclusion criteria: Pregnancy, other types of arthritis, pacemaker, metal allergies, haemophilia or other serious illness, any skin condition likely to influence the use of acupuncture needles.</p>	<p>Group C: Control group, offered acupuncture treatment after 5 weeks.</p>	
Berman et al 2004	<p>Random allocation: Yes. Concealed allocation: Yes. Baseline comparability: Yes. Blind assessors: Yes. Blind participants: Unclear. Blind acupuncturists: Not possible. Adequate follow up: Unclear. Intention to treat analysis: Yes. Between group comparisons: Yes.</p>	<p>Number of participants: 570 Inclusion criteria: Aged 50 yrs or more, radiological diagnosis of knee OA (Kellgren grade 2 or more), clinically significant knee pain on most days for 1 month or more, willing to be randomly assigned. Exclusion criteria: other serious medical conditions, intra-articular injections of steroids or hyaluronate, knee surgery or use of topical capsaicin cream in 6 months, previous experience of acupuncture, any planned events that would interfere with the study.</p>	<p>Group A; Acupuncture treatment over a 26 week period. Group B: Sham acupuncture at distal non-acupuncture points and non piercing needles applied to true acupuncture points. Group C: Control group, receiving educational sessions.</p>	<p>1. Objective and subjective rating of pain and stiffness using WOMAC score. 2. Short Form Health Survey and patient global assessment. 3. Measurement of a 6 minute walk. 4. Subjective reports of adverse effects potentially related to acupuncture.</p>

Glossary of Terms

- Bi-Syndrome* Signifies blockage or obstruction from stagnation of *Blood* and *Qi* in the *Meridian* network. It primarily gives rise to pain, swelling and restricted movement.
- Blood* A dense and material form of *Qi*. Inseparable from *Qi*. Without *Qi*, *Blood* would become an inert fluid.
- CF* Denotes Constitutional Factor, within a person, the weakest *Element* of their being and the focus of Five Element treatment.
- Cun* A measurement used for point location that involves dividing parts of the body up into equal measurements.
- Cupping* A treatment using suction to disperse stagnation and promote flow of *Blood* and *Qi*. In *Bi-Syndrome*, it can draw out wind cold damp (in recently diagnosed cases).
- De-qi* A sensation of tingling, numbness or heaviness after the acupuncture needle has been inserted.
- Dao* The principle underlying and organising creation. In terms of health it embodies the concept that living one's life in accordance with one's true nature is the key to health and happiness.
- Five Elements* Consisting of Wood, Fire, Earth, Metal and Water, and exemplified by seasonal cycle, they form five different qualities of *Qi*.

<i>JingLuo</i>	The Chinese term for <i>Meridian</i> . <i>Jing</i> is channel and <i>Luo</i> is collateral.
<i>Ke Cycle</i>	The cycle of 'control' between the <i>Elements</i> .
<i>Meridian</i>	Passage or pathway of <i>Qi</i> energy in the body along which are located acupuncture points.
<i>Moxabustion</i>	Moxa is a herb used in treatment to warm a patient
<i>Official</i>	Organ, but incorporating a wide range of functions including emotions
<i>Qi</i>	Energy or life force.
<i>Sheng Cycle</i>	The cycle of 'creation' that flows between the <i>Elements</i> as a microcosm of the seasons
<i>Yin and Yang</i>	When the <i>Dao</i> is divided, <i>Yin</i> denotes the passive principle and <i>Yang</i> the active.