



Comparison the effect of lateral wedge insole and acupuncture in medial compartment knee osteoarthritis: A randomized controlled trial



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ABSTRACT

Background: There is lack of well-designed trials evaluating structural benefits of non-pharmacologic therapies in knee osteoarthritis (OA). In this parallel-group randomized controlled trial, we aim to compare the possible advantages of lateral wedge insole and acupuncture in patients with medial knee OA.

Method: Patients with grade two or three of medial knee OA were randomly allocated to group one who received an in shoe lateral wedge and group two who underwent acupuncture. We assessed patients' pain, function and knee joint cartilage thickness before and after intervention. Paired *t*-test and independent samples *t*-test were used for in group and between group analyses. (Level of evidence: 2.)

Results: Twenty patients in each group were recruited in the study. Pain significantly decreased after therapy in both groups one and two (paired *t* test, $P < 0.001$, 95% CI: 1.62–3.25 and 1.58–3.20 respectively). Function improved in each group (paired *t* test, $P = 0.001$, 95% CI of 0.94–2.38 in group one and 0.97–2.43 in group two). A non-clinically statistically significant difference regarding the femoral and tibial cartilage thickness was obtained in both groups one ($P = 0.005$, CI: -0.43 – 0.82 and $P = 0.037$, CI: -0.44 – 0.80 respectively) and two ($P = 0.025$, CI: -0.45 – 0.79 and $P = 0.035$, CI: -0.29 – 0.96 respectively). Between groups analysis showed no significant difference regarding abovementioned measures.

Conclusion: Both lateral wedge insole and acupuncture can be effective in the treatment of medial knee osteoarthritis without any superiority of one over the other.

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1. Introduction

Knee osteoarthritis (OA), which most commonly affects the medial compartment [1], is one of the major causes of pain and physical disability in the elderly and it is estimated that it involves almost 10–13% of those over 65 years with a consequent major healthcare burden [2,3]. Although the role of biomechanical factors in the pathogenesis of knee OA has been well described [4], according to the findings of a meta-analysis conducted in 2000, about 86% of OA trials evaluate drug treatments or assess surgical procedures [5]. This has prepared lucrative opportunities for the development of drug therapies, in the absence of sufficient evidences to support rehabilitation and physical therapy

techniques [6,7], in spite of the fact that probably, overall there is no, at least statistically, considerable disparity between non-pharmacological therapies and pharmacological therapies [8]. Bearing the adverse effects of the most frequently used existing medications in mind, we should aspire to increase the use of rehabilitation therapies if we are to prove their safety and efficacy.

Previous observational studies were suggestive for the advantageous effect of lateral wedge insoles for patients with medial tibio-femoral compartment OA [9–12]; yet, these findings have not been supported by conducted randomized clinical trials and no structural protection pursuing the utilization of lateral wedge insoles has been observed [6,13–16]. Nevertheless, the use of lateral wedge insoles for patients with medial knee OA is recommended in most of existing guidelines for the management of knee OA [8]. Acupuncture is also a suggested modality for symptomatic treatment of patients with knee OA in many guidelines [8]; nonetheless, a systematic review of the evidence for the efficacy of acupuncture in knee OA which included seven RCTs

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and 393 patients recommended that observed improvement in function of patients after acupuncture was inconclusive [17]. Also a very recent RCT in 352 patients with knee OA has shown very small, statistically significant, improvements in pain severity in patients, two and six weeks after acupuncture [18]. Synopsis of the evidences has suggested that a minimum number needed to treat with acupuncture for clinically significant relief of pain in patients with knee OA is four [8].

To the best of our knowledge, most of the previously conducted studies regarding the effects of acupuncture and laterally wedge insoles were mainly based on subjective variables such as gained score using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or visual analog scale (VAS), other than objective variables such as measurement of knee articular cartilage thickness by magnetic resonance imaging (MRI). As a result, their findings may be inconclusive and not reliable. So, we presume to perform a study, to assess and compare the effects of lateral wedge insoles and true acupuncture on subjective and objective findings of the patients with medial knee OA.

2. Material and methods

2.1. Design and participants

We designed a parallel randomized controlled trial with the allocation ratio of 1:1 and recruited participants from the individuals seeking care at the physical medicine and rehabilitation clinics of hospitals affiliated to our university who said that they were interested in participating in research. The trial was conducted from May 2012 to January 2013.

Diagnosis of osteoarthritis was made by an expert physiatrist with regards to the American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the knee joint [7,19]. The eligibility criteria for inclusion in the study were as follows: age between 38 and 65 years, successive knee pain unresponsive to conventional treatments for at least three months, and radiological findings are consistent with medial compartment knee OA, grade two (small osteophytes, possible narrowing of the joint), or grade three (multiple, moderately sized osteophytes, definite joint space narrowing, some sclerotic areas, possible deformation of bone ends) of the Kellgren–Lawrence classification system.

Patients were excluded if they had undergone initiation of other medical therapies with possible effects on the volume of knee articular cartilage (for example glucosamine and/or chondroitin); had symptomatic comorbid disease that limited walking more than knee pain limited walking (diabetic neuropathies, inflammatory arthritis, foot ulcers or sores, experienced pain emanating more from the back or hip than from the knee, vasculitis); had undergone amputation of or previous major trauma to a foot, raising apprehensions that using an insoles may deteriorate the pain; had any previous knee surgery; were chair-bound or usually used an ambulation aid to walk; had been using oral or parenteral steroids; had contraindications to magnetic resonance imaging or had severe knee joint osteoarthritis.

Every patient signed an informed consent form and the study protocol was approved by our university's ethics committee (no. ct-90-2690).

2.2. Interventions and measurements

Every patient in group one; for the side of the affected knee; received an in shoe wedge with the maximum of 5 mm (millimeter) thickness in the lateral heel which was tapering to the 2 mm thickness towards the anterior and medial sides of the sole and continued up to the metatarsal heads. Patients in this group were instructed to use the wedge in an appropriate shoe (not high heels or narrow-toed shoes) 1 h a day during the first week. The duration of use gradually increased to the minimum of 8 h a day. Patients were followed with telephone calls every 45 days during the study period. The patients' convenience was assessed and reported throughout the study (Table 1).

Acupuncture was performed for patients in group two with eight needle insertions per patient per session for total duration of 10 sessions using 0.25 × 25 mm stainless steel needles. We selected the acupuncture points based on Traditional Chinese Medicine meridian theory as following [20]:

- 1) EX.31 (Heding): above the knee in the depression of the midpoint of the superior patellar border
- 2) EX.32 (xiyan): below the patella in the hollow at medial side of the patellar tendon
- 3) ST.35 (Dubi): lower border of the patella in the depression lateral to the patellar ligament
- 4) ST.36 (Zusanli): 3 cun below the knee, about one fingerbreadth from the tibial tuberosity
- 5) ST.44 (Neiting): on the dorsum of the foot, proximal to the web margin between the second and third toes
- 6) GB.34 (Yanglingquan): in the lateral side of the leg in the hollow anterior and below the capitulum of the fibula, 2 cun below the knee
- 7) DU.20 (Baihui): at the intersection of the median line at the vertex of the head with a line drawn from the tip of one ear to the other
- 8) BL.60 (Kunlun): in the depression between the apex of the lateral malleolus and Achilles tendon.

Acupuncture was done by a trained physical medicine and rehabilitation resident with a two-year practice and during all sessions, the depth of insertion, and the intensity of stimulation (manipulation) were kept identical. The needles remained in the patients' body for 30 min in each session.

We assessed patients' pain and function in addition to knee joint cartilage thickness before and after each intervention. The total duration of intervention was three months for group one and three weeks for group two (three sessions per week) and outcome measurement was done in another session immediately after the end of each intervention predetermined period. Pains during movement over the past week were measured by the visual analog scale (VAS) from zero to 10 in 1 cm intervals (zero: no pain, 10: greatest pain imaginable). The WOMAC scale was used to investigate functional status. This scale evaluates patients' function during different activities like sitting, standing and walking and consists of five questions regarding the level of pain experienced during a particular activity over the past 48 h. Every question can have five different answers that take different scores from zero to four (zero: no pain, one: mild pain, two: moderate pain, three: severe pain, four: very severe pain). Final score for each patient is calculated through summation of all five parts' scores.

Patients' joint cartilage thickness before and after every therapeutic intervention was measured by a Siemens Avanto magnetic resonance imaging (MRI) scanner with Tim 32 × 8 with proton density-weighted imaging with a slice thickness of 3 mm, field of view of 14 cm, matrix of 358 × 512, TR: 2700, TE: 36, slice gap: 0.6, signal average: 2, bandwidth: 191 and Turbo faster: 10. This measurement was done in the medial compartment of the posterior inferior portion of the femoral condyle and posterior portion of the tibial plateau simultaneously.

Table 1

The scoring system for reporting patients' convenience regarding the use of lateral wedge insole.

Score	Level of discomfort
0	None
1	Mild
2	Moderate
3	Severe
4	Very severe

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