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Critical Systematic Review: The effectiveness of lateral wedged insoles in knee osteoarthritis

Abdullah Arabe[1]; Amira Alrshood[1]; Salima Enaiba[2] and Adel Almangoush[2]
1- Ministry of Health Kingdom of Saudi Arabia - Saudi Arabia
2- Faculty of Medical Technology– Misurata – Libya

Abstract
Objectives: *The purpose of this review was to determine the clinical effectiveness of lateral wedged insoles in the management of medical treatment of people with knee osteoarthritis.*
Search methods: *Several databases were searched from 2007 to 2018: Medline, AMED, EMBASE and the Cochrane Library and Cochrane Controlled Trials Register. The search terms used included knee, foot, insole, medial arch, arch support, osteoarthritis, shoe, laterally wedged insole, conservative management, medical wedge, physiotherapy and rehabilitation. search terms with 'and' and 'or' Boolean connectors were used as well.*
Data collection: *The primary literature searches of the electronic databases used in this review resulted in a total of 94 potentially relevant papers. After screening of the titles and abstracts 44 studies were excluded as they did not meet the inclusion criteria. The full texts of the remaining fifty trials were downloaded and then carefully screened. The record of remaining fifty articles and removal of duplicates which have been made between databases left only 5 full text papers were regained and only one study was analysed according to the inclusion and exclusion criteria.*
Conclusion: *one of the most common condition affecting the knee joint is osteoarthritis, which leading to loss of function and pain in the knee. The first treatment option should be used is Conservative treatment options with the patient in question, using validated measures.*

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I. Introduction

Osteoarthritis (OA) is one of the most common rheumatic conditions that can affect the knee joint; which can lead to disability and severe pain (Dillon, 2006). It is defined as "degeneration of joint cartilage and the underlying bone, most common from middle age onward. It causes pain and stiffness, especially in the hip, knee, and thumb joints" (Dictionaries, 2015). The knee is the joint most affected in many of the developed countries (Jones et al., 2004).

According to present studies, almost 8.5 million of the population in United Kingdom (UK) have been diagnosed with OA (Chen et al., 2012). It is common among elderly people, however, symptoms related to OA are reported by up to one third of the population in earlier life (Felson. 1990, Lawrence et al., 1998). Above the age of 45 years, and by the age of 60 around 30-40% of the population are affected. In approximately 20-28% of the UK population around the age of 40 with knee pain, it is suggested that 50% of these will go on to develop OA (Peat et al., 2001). Hence, due to it being a common health problem there is the potential for it to have many consequences. This is in terms of impact on the individual in relation to symptoms, limited mobility and reduced activity. In terms of social cost, the knee and hip are one of the costliest to manage in relation to OA of other joints, with the knee being the greater cost (Jinks et al., 2004; Bijlsma and Knahr, 2007) hence a cost to health services.

In elderly people knee OA is a widespread disease that contributes significantly to the functional limitations of these people. There are many physical signs accompanying knee OA such as decreased quadriceps femoris muscle strength, pain and loss of motion (Kelley et al, 2002). Biomechanically increased mechanical stresses and forces, muscle weakness and altered loading mechanisms are important factors to the onset of OA (Egloff et al., 2012). The medial compartment of the knee is the area most affected by OA (Laroche et al., 2014). In around 76-93% of the patient diagnosed with OA go on to develop a varus deformity of the foot (Cooke et al., 2002). The first choice of treatment in early OA usually involves non-operative measures unless there are lesions present, in which case surgery may be considered (Kon et al., 2012). Modifying lifestyle such as reducing weight, using supportive orthotics such as insoles and a knee brace, anti-inflammatory drugs, Physiotherapy, exercise, and intra-articular injections including steroids that will restore haemostasis of the joint and reduce the pain (Kon et al., 2012). However, those with OA of the knee joint tend to have weak quadriceps

muscles, which will not provide the support needed to cope with any excessive forces or loads (Wessel, 1996; Fisher and Pendergast 1997; Hurley et al., 1997; O'Reilly et al., 1998), therefore other interventions may be necessary. The purpose of this review was to determine the clinical effectiveness of lateral wedged insoles in the management of medical treatment of people with knee osteoarthritis.

II. Method

In order to find the information to produce this review several databases were searched from 2007 to 2018: Medline, AMED, EMBASE and the Cochrane Library and Cochrane Controlled Trials Register. The search terms used included knee, foot, insole, medial arch, arch support, osteoarthritis, shoe, laterally wedged insole, conservative management, medical wedge, physiotherapy and rehabilitation. search terms with 'and' and 'or' Boolean connectors were used as well. PubMed was used initially to look for some background information regarding Osteoarthritis of the knee and the current treatments that are used, using the search phrase "effectiveness of lateral wedge insoles in knee osteoarthritis".

All published controlled trials recruiting subjects with a diagnosis of knee osteoarthritis and assessing the use of lateral wedged insoles were included. Papers testing patients with lower limb fractures or neurological disorders such as stroke were excluded. The primary literature searches of the electronic databases used in this review resulted in a total of 94 potentially relevant papers. After screening of the titles and abstracts 44 studies were excluded as they did not meet the inclusion criteria. The full texts of the remaining fifty trials were downloaded and then carefully screened. The record of remaining fifty articles and removal of duplicates which have been made between databases left only 5 full text papers were regained and only one study was analysed according to the inclusion and exclusion criteria.

Title	Author	Participants	Intervention	Control	Outcome	Provide a brief overview of what they are saying
Walking shoes and laterally wedged orthoses in the clinical management of medial tibiofemoral osteoarthritis: A one-year prospective controlled trial	Barrios et al. (2009)	66 patients 37 females 29 males Mean Age 62.4years	Single blind block randomised trial. - Control Group Treatment Group		The use of neutral controlled orthoses in conjunction with walking shoes and lead to significant clinical improvement in subject with MOA	Both neutral and laterally wedged orthoses may be beneficial in the management of medial knee OA when used with waking shoes
A Randomized Crossover Trial of a Wedged insole for treatment of Knee Osteoarthritis	Baker et al. (2007)	90 patients 50 years	Treatment A – Flat 1/8-inch-thick shoe insert on side of affected knee Treatment B – 5 degree lateral wedge insole on side of affected knee	Staff performing clinical examination blinded to the treatment assignment	The mean different in pain between the 2 treatment was 13.8 points on the (WOMAC)	They did not found that the use of a lateral –wedge insoles for 6 weeks created problems in the foot or elsewhere in the body
The relationship between reductions in knee loading and immediate pain response whilst lateral wedge insoles in knee osteoarthritis	Jones et al. (2014)	70 patients 45 years and above	Average decreases in medial loading Important in medial load Medial load reduction		There is no clearcut relationship between change in medial load when wearing LWIs and corresponding change in knee pain	The lateral wedge insoles reduce the adduction moment across the knee in those with medial OA but they do not lessen knee pain
Lateral wedge insoles for medial knee osteoarthritis: 12 month randomized controlled trial	Bennell et al. (2011)	200 patients Age 50 or more	Full length 5 degree lateral wedged insoles or flat control insoles wren inside the shoes daily for 12 month		The primary outcome was change in overall knee pain measured on an 11 point numerical rating scale	Lateral wedge insoles worn for 12 mounts provided no symptomatic or structural benefits compared with flat control insoles
Laterally wedged insoles in knee osteoarthritis: do biomechanical effects decline after one month of wear?	Hinman et al. (2009)	20 patients	Gait in their own shoes wearing on insoles and insoles wedged laterally 5 degree in random order		There was a significant main effect for condition, whereby significantly reduced the adduction moment	Effects of laterally wedged insoles on the adduction moment do not appear to decline after one month of continuous

variations.
The five selected trials were as follows:

The information from each paper was put into a table in order to do a preliminary comparison of the studies, and then one paper was chosen to critique.

Critique

The study uses a list of exclusion criteria which it identifies as:

Participants were recruited from printed advertisements that were posted in Doctors surgeries, physical therapy centers, and wellness clinics and in local newspapers and other circulations. This shows a wide range of participants sought from more than one place increasing the likelihood of criteria to be matched with a reasonable number of participants. The number of total participants for the study was sixty-six.

Participants were categorized into groups based on OA grade, gender and age (greater than or less than 55 years of age). (Barrios et al., 2009) however, all the previously mentioned methods suffer from some serious weaknesses. The study would have been more useful if he used 200 participants the age around 50 and more also assess the pain while they walking using the 11-point scale which sows (0 = no pain 11= worst pain possibly) (Bennell et al., 2011). More recent arguments against number of participants have been summarised by Baker and his Colleagues (2007) for the 3 following sources the previous history of the natural study, for those how said they are interested in the participation research they listed individually at local facility also the local newspaper was adding an advertisement about the study and 90 participants were recruited. However, there is an inconsistency with this argument different size of wedge has been chosen for different size of foot for the small foot they chose size 6-8mm and for the large foot they chose size 9-12mm (Barrios et al., 2009). Most studies in the field of Knee OA management have only focused on 5-degree wedge insoles (Bennell et al., 2011) within the normal shoes it is too difficult to accommodate insoles with the wedge greater than 5 degrees. In addition, Jones and co-workers (2014) shows that to ensure fitting the 5^{th} metatarsal into the toe box of the shoes and to contralateral limb of all participant 5-degree lateral wedge insoles must been used. While some research has been showmen the insoles material if it from high density ethyl vinyl used, and worn bilaterally in side the shoes with 5-degree wedge can help to reduced the pain in Knee OA (Hinman et al., 2009).

Statistical

Simple statistical analysis was used to in these study different type of the statistical test was used such as student's t-test which used to test the age and the BMI in different group, for the K-L grade pronation in different group Chi-square test of independence was used, the Fisher's exact test used to measure the gender proportion at difference group, the last test was used pragmatic trial for an intervention, and an intention to treat. (Barrios et al., 2009) These studies would have been more useful if they had focused on tow different group in this study was assisting in different mouthed (K/L grade 4) used with OA patient because obesity one of the strong factors for OA the (BMI>30kg/m) used between the obese and non-obese patient in the second group. (Baker et al., 2007). In this useful study (Version 11) state was used for all the analysis and the P values of the less than 0.05 to be significant. For compered the difference in mean changes between groups they used the linear regression modeling adjusted for baseline values of the outcome also to continuous the outcome measure. (Bennell et al., 2011).

III. Result

The results of the correlational analysis are there is similarity between the all groups for K-L grade proportion (p=0.650) and gender proportion (p=0.807) the BMI (p=0.212) and age (p=0.778). The amount of the wedging increased progressively with K-L grade, 9.1degree (SD3.9 degree) was the average amount of wedging which is necessary to produce the maximum amount of pain relief in the treatment group (Barrios et al., 2009). However, Blister which appear on the top of the toes when the wedge pushed feet up it is the most common side effect of the wedge in the shoes (Baker et al., 2007).

IV. Conclusion

This study has shown that one of the most common condition affecting the knee joint is osteoarthritis, which leading to loss of function and pain in the knee. The first treatment option should be used is Conservative treatment options with the patient in question, using validated measures. If these measures fail, patient may have to be offered to surgical. However, for a short period of time to delay needing for surgery the Lateral wedged insoles maybe is better selection to reduce pain and improve function.

Depend on severity level of disease and the range of compartment included the treatment of knee OA. Most of the Varus deformity in the knee it is in the medial side of the knee compartment. 5-dgree Lateral

wedged insoles have been discussed in this paper. 5-dgree Lateral wedged insoles appear to be effective to reduce adduction moment in the knee joint biomechanically and clinically, which has been significantly associated with OA progression as well as initiation.

V. Recommendations

- Comprehensive systematic review to investigate the effectiveness of lateral wedged insoles in knee osteoarthritis is urgently Recommend. This may form the basis for my hypothesis in the MoE dissertation.
- Furthermore, future research should also include placebo controlled trials to ascertain the efficiency of various interventions.
- Indeed further research could do a lot to clarify what is at present a plethora of 'poor' quality evidence.

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