A meta-analysis into the effect of lateral-wedged insoles with subtalar strapping versus traditional insoles in adults with medial knee osteoarthritis.

Duvenhage L, BSc[1]
Mushaike T, BSc[1]
Parker N, BSc[1]
Swartz L, BSc[1]
Van Rensburg M, BSc[1]
Wilkinson S, BSc[1]
Morris L, BSc, MSc[1]

[1] **Stellenbosch University**

ABSTRACT: *To systematically identify, collate, and analyze the current available evidence for the effectiveness of lateral-wedged insoles, with subtalar strapping, on reducing pain, improving function and improving the femoral-tibial angle (FTA), in adults with medial knee osteoarthritis compared to traditional insoles without subtalar strapping.*

Six computerised databases, namely Cochrane Library, CiNAHL, PEDro, BIOMED central, PubMed and ScienceDirect were searched. The included articles were then all rated using the PEDro scale to determine their methodological quality. Homogeneous data were pooled in a meta-analysis using Review Manager (REVMAN) software. Where statistical pooling of the results was not possible, findings were summarised in narrative form.

Three randomised controlled trials were selected for this review. The average PEDro score was 5.7. A meta-analysis demonstrated that lateral-wedged insoles with subtalar strapping significantly reduced pain in the short-term (p=0.004).

The review found that lateral-wedge insoles with subtalar strapping significantly decreased pain in the short-term and seemed to have a positive effect on the FTA in the long-term, when compared to traditional insoles without subtalar strapping. The lateral-wedge insole with subtalar strapping may provide a financially feasible adjunctive self-management treatment for knee OA and should be considered before invasive procedures such as surgery.

KEY WORDS: LATERAL-WEDGES INSOLES, SUBTALAR STRAPPING, MEDIAL KNEE OSTEOARTHRITIS.

INTRODUCTION

Osteoarthritis (OA) is a chronic degenerative joint condition, characterized by the progressive loss of cartilage. It is arguably, the most prevalent joint disorder in developed and developing countries and is a major cause of functional disability (Das and Farooqi 2008; Zhang and Jordan 2008). The most common joint affected by OA is the knee; with the anatomic medial compartment most often involved (Ledingham et al 1993). Patients with knee OA typically suffer from knee pain and difficulty with functional activities, which often leads to days off work, increased healthcare utilization and a diminished quality of life (Das and Farooqi 2008). The economic burden of knee OA to industry, healthcare system, state and society is therefore of concern, and warrants cost-effective approaches to treatment (Sasaki and Yasuda 1987).

Physiotherapy is traditionally a common conservative treatment for knee OA, which aims to reduce pain, improve function, decrease abnormal forces acting on the medial knee compartment, and possibly delay or reverse the degenerative process (Marks and Penton 2004). However, since multiple treatments are often required over time, physiotherapy can become costly to the state and the individual. As primary care practitioners, it is therefore imperative that physiotherapists are aware of their limitations in treating chronic conditions and are able to recommend self-care treatment options which may encourage patients to actively participate in their own management. Orthoses are self-administered devices mainly used to correct the mal-alignment and reduce the progression of the degenerative process of OA. Patients are able to use orthoses in the comfort of their home and are ultimately responsible for their own health. Subsequently, the number of physiotherapy sessions required is decreased and ongoing healthcare costs reduced. Clinically, socially and financially it may therefore be advantageous to recommend orthoses to patients with knee OA (Hurley and Walsh 2001).

In patients with medial knee OA, orthoses like lateral-wedged insoles with

Correspondence to:
LD Morris,
Division of Physiotherapy,
Department of Interdisciplinary Health Sciences,
Faculty of Health Sciences,
Stellenbosch University,
P O Box 19063 Tygerberg 7505
Republic of South Africa
E-mail: ldmorris@sun.ac.za

inclinations of 5°-12°, are commonly recommended. The insole creates an inclination of the existing floor, resulting in improved standing and walking conditions. Once the patients have adapted to these conditions, changes in balance produce a new walking and standing pattern. The premise if that after the insertion of the lateral-wedged insole, the line through the centre of gravity runs through the lateral side of the sole. The femoral-tibial angle (FTA) is thus displaced in the valgus direction with the calcaneus similarly displaced and the inclination of the weight-bearing lower limb is favourably altered. The change in the spatial position of the femur, tibia and calcaneus, results in a more upright position of the mechanical axis of the lower limb which decreases the load on the medial knee surfaces. This decrease in the knee load eventually results in a decrease pain and an improvement in function (Sasaki and Yasuda 1987).

However, the use of a lateral-wedged insole on its own allows movement to occur at the talus thus preventing the correction of the FTA. This shortcoming was addressed through the use of a lateral-wedged insole with subtalar strapping (Toda et al 2005). Some evidence has been found that the use of subtalar strapping combined with lateral-wedge insoles has a greater effect on pain reduction as well as speed of ambulation. Subtalar strapping, when used in conjunction with lateral-wedge insoles, has shown to be a more effective conservative approach in the treatment of mal-alignment and medial knee OA pain when compared to other forms of strapping such as talonavicular strapping. Biomechanically, the addition of the subtalar strapping has led to the decrease in the talar tilt angle as well as improving the FTA and regulating medial compartment loading (Toda and Segal 2002).

Although a review reporting on the effectiveness of lateral-wedge insoles for medial compartment knee OA was published in 2006, the review did not include studies reporting on the use of lateral-wedge insoles in combination with subtalar strapping (Reilly et al 2006). The aim of this review was thus to systematically identify, collate, and analyze the current available evidence for the effectiveness of lateral-wedged insoles, with subtalar strapping, on reducing pain, and improving function and knee biomechanics (namely the FTA), in adults with medial knee OA compared to traditional insoles without subtalar strapping.

METHODOLOGY

Search Strategy

The following computerised bibliographic databases were searched during March 2009 via the Stellenbosch University library service: Cochrane Library, Cinahl, PEDro, PubMed, Science Direct and BioMed Central (BMC). An update of the search was conducted prior to submission for publication. The six databases were divided between the six reviewers who then performed a detailed independent search using the following key terms: *medial knee osteoarthritis, subtalar strapping and lateral wedge insole/ orthotic*. Since each database has its own indexing terms and search functions, different search strategies were developed for each database. The complete search strategy has been included in Appendix 1. The findings of each database were cross-checked and verified by another reviewer from the group. Titles and abstracts of studies meeting the inclusion criteria were obtained and independently reviewed by two reviewers in each group. Disagreement was resolved by discussion or by arbitration by a third reviewer from another group before the full text articles were obtained.

Criteria for considering eligible studies (inclusion and exclusion criteria)

All relevant English randomized controlled trials (RCTs) reporting on the effect of lateral-wedge insoles with subtalar strapping on reducing pain, and improving function and knee biomechanics (specifically the FTA) in adults with medial knee OA, compared to traditional insoles without subtalar strapping were considered for inclusion in this review. Only studies reporting on lateral-wedge insoles with subtalar strapping with an incline of 5 to 12 degrees, as the intervention for reducing pain, disability and knee varus torque in adults with medial knee OA were eligible for inclusion in the review. Case studies, laboratory or analogue studies, and systematic reviews were excluded from this review. Participants were limited to male and female adults, age 18 and older, with a documented diagnosis (as well as a radiographic confirmation of the diagnosis) of medial knee OA (medial but not lateral tibio-femoral narrowing, unilateral or bilateral). Participants receiving non-steroidal anti-inflammatory drugs or any other analgesics during the trials were also included. Participants were not limited to any specific race and culture. Participants who used any type of wedged insole or walking aid prior to the trial; had limited ability to wear shoes; had neuropathies due to diabetes or other causes, had symptomatic co-morbid diseases that limited walking more than knee pain limited walking, or were unwilling to start any new medication during the trial period; had any knee, hip or ankle surgery (such as an arthroscopy and osteotomy); suffered from peripheral or central nervous system diseases; had hip, lumbar spine and ankle OA; had or still suffers from secondary knee OA or any other symptomatic deformity or pathology of the foot and ankle; had any other disease treated with insoles; and had received intra-articular injections in the last 6 months, were excluded from this review. Outcomes for the review included, but were not confined to: 1) Pain, as measured with a Visual Analog Scale (VAS) or any similar pain measurement scale; 2) Function, as measured with the Lequesne index, physical performance measures such as 50-feet walk time, 5 chair-stand time or any similar measurement scales; and 3) Pain and function combined, as measured with the Lequesne index; and 4) FTA as measured radio-graphically.

Study quality assessment

Level of Evidence

The level of evidence of the eligible RCTs included in the review were assessed using the rating guidelines of the National Health and Medical Research Council (2000) (see Table 1). Each RCT was independently assessed by a group consisting of two reviewers each. A third reviewer from a different group was consulted if a consensus was not reached.

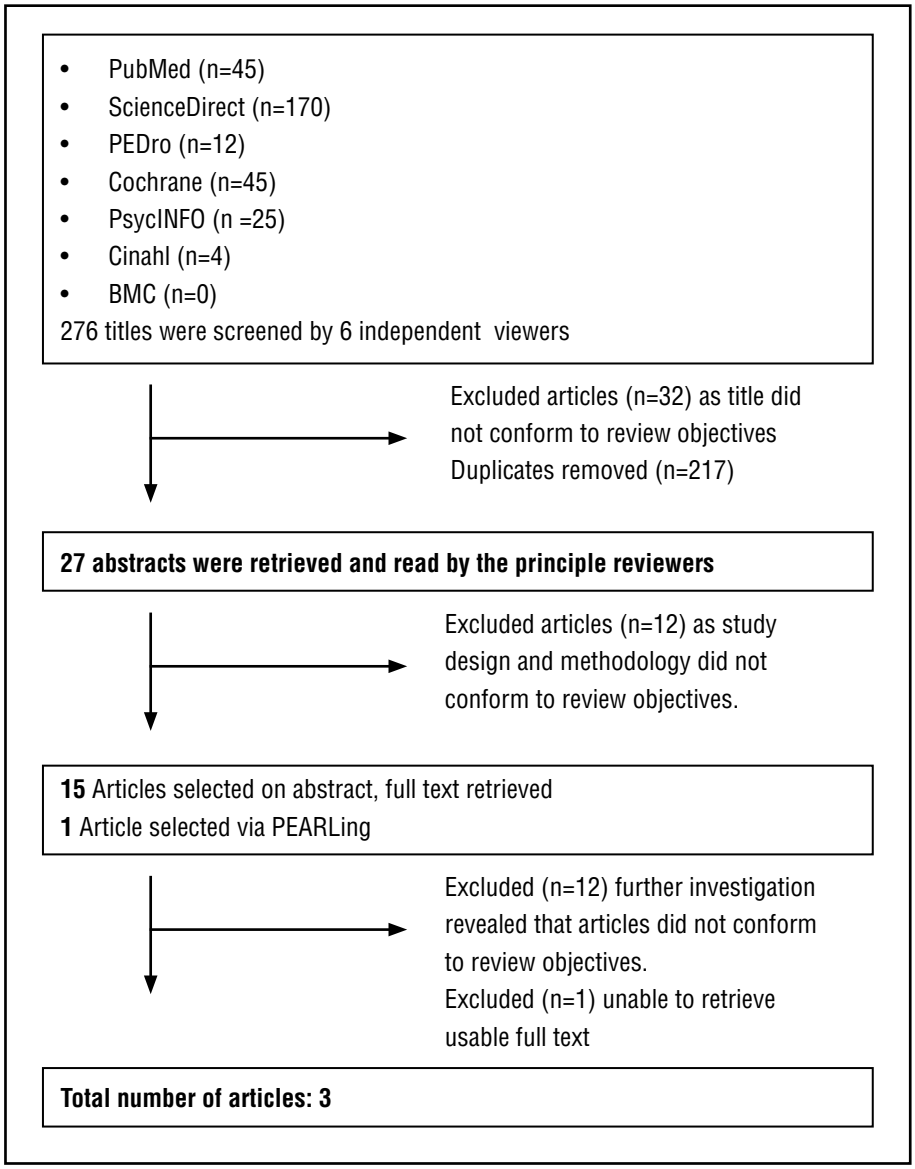
Table 1: National Health and Medical Research Council Guidelines (2000)

Study design	Level of evidence
Systematic review of all relevant randomised controlled trials (RCT)	I
Properly designed RCT	II
Well-designed pseudo-randomised controlled trial (e.g. alternate allocation)	III-1
Comparative studies (or systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group	III-2
Comparative studies with a historical control, two or more single arm studies or interrupted time series without a parallel control group	III-3
Case series, post-test or pre-test/post-test, with no control group	IV

Methodological Appraisal

The 'PEDro scale' was used to critically appraise the methodological quality of each study. The PEDro scale consists of a checklist of eleven criteria which are based on the Delphi list that was developed by Verhagen and his colleagues (Verhagen et al 1998) and is able to assist researchers in determining the validity of the study as well as whether the statistical information is adequate and can be used for analysis. Each item requires a yes/no response, with a yes response being allocated one point, and a no/unclear response being allocated zero points. Two independent reviewers critically appraised each selected study. A third reviewer was consulted if no consensus could be reached.

Figure 1: Consort Diagram for database search results



Data Extraction

Each reviewer in each group, independently extracted the following data: authors' names, year, country of publication, the study design; number of participants; type of participants, types of intervention; outcome measures; outcome measurement time-periods (short-, mid- and long-term), the quality of the study (based on the PEDro scale) and level of evidence, and the effect of the lateral-wedge insole with subtalar strapping on pain, function and knee biomechanics. Where certain information was lacking, the reviewers attempted to contact the researchers via e-mail to obtain the necessary information. Only one of the authors contacted, replied in time.

Data Analysis

The studies were assessed for homogeneity by considering type of populations, condition, interventions and the outcomes. A meta-analysis could be performed for the outcomes: pain, pain and function and FTA, in the short-term, due to sufficient homogeneity between the studies. In addition, where the included studies provided sufficient data, such as means and standard deviations (SD), 95% confidence intervals (CIs) were calculated around the mean differences using Review manager (REVMAN). 95% CIs were calculated for the effect of the lateral-wedge insoles with subtalar strapping over time (at short-, mid- and long-term) to demonstrate the effect over time.

Table 2: Methodological appraisal results of included studies

PEDro criteria	Toda et al 2001	Toda & Tsukimura 2004(b)	Toda & Tsukimura 2006
Eligibility criteria were specified	+	+	+
Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	+	+	+
Allocation was concealed	-	-	-
The groups were similar at baseline regarding the most important prognostic indicators	**+**	-	+
There was blinding of all subjects	-	-	-
There was blinding of all therapists who administered the therapy	-	-	-
There was blinding of all assessors who measured at least one key outcome	**+**	-	-
Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	**+**	**+**	-
All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by **"intention to treat"**	**-**	-	-
The results of between-group statistical comparisons are reported for at least one key outcome	+	+	+
The study provides both point measures and measures of variability for at least one key outcome	+	+	+
Total score	7/11	5/11	5/11

Key: (+) = criteria fulfilled, (-) = criteria not fulfilled

Table 3: Overview summary of included studies

Study	Country	Setting	Study population	Sample size	Drop outs	Age range	Type of study
Toda et al 2001	Japan	Orthopaedic outcome clinic- Toda Orthopaedic Rheumatology clinic	Female ≥45 years old Outpatients seen in 2000 Diagnosis of OA knee, according to American College of Rheumatology criteria	**Strapped** 46 **Traditional** 44	0	**Strapped** Mean+-SD: 64.7+-8.8 Median:64 95%CI: 62.1-67.3 **Traditional** Mean+-SD: 65.9+-8.4 Median:67 95%CI: 63.3-68.5	RCT
Toda & Tsukimura 2004(b)	Japan	Orthopaedic outcome clinic	Females Diagnosis of Medial compartment OA knee, according to American College of Rheumatology criteria Standing FTA > 176°, determined by X-ray	**Strapped** 32 **Traditional** 34	5	**Strapped** Mean+-SD: 63.1+-7.9 Median:64 95% CI: 60 66.1 **Traditional** Mean+-SD: 66.4+-7.4 Median:68 95%CI: 63.6-69.1	RCT
Toda & Tsukimura 2006	Japan	Orthopaedic outcome clinic	Females Diagnosis of Medial compartment OA knee, according to American College of Rheumatology criteria Standing FTA > 176°, determined by X-ray	**Strapped** 24 **Traditional** 32	19	**Strapped** Mean+-SD: 63.1+-7.9 Median:64 95% CI: 60-66.1 **Traditional** Mean+-SD: 66.4+-7.4 Median:68 95%CI: 63.6-69.1	RCT

Table 4: Interventions and Comparisons

Study	Intervention	Comparison/Control
Toda et al 2001	Lateral wedged insole with subtalar strapping	Traditional shoe inserted wedged insole
Toda & Tsukimura 2004b	Lateral wedged insole with subtalar strapping	Traditional wedged insole shoe insert
Toda & Tsukimura 2006	Lateral wedged insole with subtalar strapping	Traditional shoe inserted wedged insole

Table 5: Outcome measures, measurement tools and measurement time-frame.

			SHORT-TERM			MID-TERM	LONG-TERM
Study	**OM**	**OMT**	**BL**	**8w**	**3m**	**6m**	**24m**
Toda et al 2001	FTA Pain Pain and Fx	Radiograph VAS Leq	X X X	X X X			
Toda & Tsukimura 2004(b)	FTA Pain Pain and Fx	Radiograph VAS Leq	X X X		X X X	X X X	
Toda & Tsukimura 2006	FTA Pain and Fx	Radiograph Leq	X X				X X

Key: OM=outcome measure, OMT=outcome measure tool, BL=baseline, w=week, m=month, FTA=Femoral-tibial angle, Fx=function, Leq=Lequesne index

RESULTS

Search results

The comprehensive search for relevant studies yielded 276 hits. PEARLing (where the reference lists of included/excluded studies are checked for additional studies) yielded 1 article, but the full text was not available and the article was therefore excluded. After duplicates and ineligible articles were excluded, a total of **3** articles were consequently used in this review. Figure 1 illustrates the full database search results.

Quality assessment of included studies

Level of Evidence

The three included articles were all RCTs (Toda et al 2001, Toda and Tsukimura 2004, Toda and Tsukimura 2006) and denoted level II evidence according to the guidelines established by the National Health and Medical Research Council (2000).

Methodological appraisal

The methodological quality of the three included articles ranged from five to seven out of 11 on the PEDro scale, with an average PEDro score of 5.7. Table 2 summarises how each article was scored using the eleven-item PEDro scale. During the methodological appraisal of the included articles, it was noticed that criterion 3 (concealed allocation), criterion 5 (blinding of all subjects), criterion 6 (blinding of all therapists) and criterion 9 (intention to treat) were not fulfilled in any of the three studies.

General description of included studies

Descriptive data extracted from the three eligible studies are reported as an overview summary (Table 3). All the included studies originated from Japan, and were conducted between 2001 and 2006. The sample sizes in the included studies ranged from 24 to 46 and all the participants were female. The combined mean age range was 60 to 67 years.

Intervention and comparisons

Table 4 details the intervention and comparison for each included study. All studies compared a lateral-wedged insole with subtalar strapping to a traditional insole. All the studies made use of additional intervention consisting of NSAID therapy administered twice daily. In Toda and Tsukimura (2004) participants were given the option to discontinue adjunctive therapy. All the studies described the traditional insole as an insole with a lateral-wedge made from rubber material. Two studies (Toda and Tsukimura 2004; Toda and Tsukimura 2006) specified that the inserted insole consisted of a nylon seat, adhesive tape, and a lateral sponge-rubber wedge.

In all three studies the lateral-wedge insole with subtalar strapping consisted of a lateral-wedge made of urethane and an ankle support band with adhesive tape twisted into a figure 8 around the ankle and subtalar joints. However, in Toda et al (2001) an insole strapped to an ankle sprain supporter fitted around the ankle and subtalar joints, was used. One study (Toda et al 2001) made use of lateral-wedged insoles with an elevation of 6.35mm (tilt angle 5˚) compared to the other two studies (Toda and Tsukimura 2004; Toda and Tsukimura 2006) which used a lateral-wedged insole with an elevation of 12mm.

Outcome measures and tools

In the included studies, the following outcome measures were measured in the short-, mid- and long-term: pain, pain and function (combined), and FTA. The outcome measurement tools and measurement time-frames for pain, pain and function, and knee biomechanics (FTA) are presented in table 5. Summers (2001) tested the reliability and validity of the VAS and found it to be an adequate outcome measure for assessing pain. The Lequesne index has a good test re-test reliability and was found to be an excellent assessment tool for measuring pain and function in knee OA (Faucher et al 2003).

Patient outcomes

Two studies were found to be homogenous in population, condition, intervention, comparison as well as outcome measures and tools. The third study provided sufficient data, namely the means and SD's, which could be used to calculate the 95% CI's around the mean differences and pool data together in the

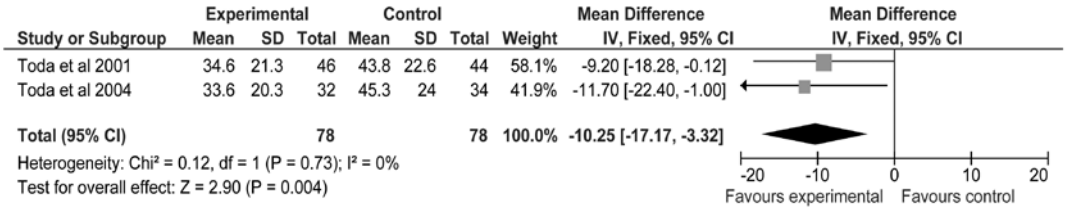
REVMAN program. The patient outcomes: pain, pain and function, and FTA for short-, mid- and long-term is reported below. In the graphs 'experimental' is the lateral-wedge insoles group and the 'control' is the traditional insole group.

Pain At short-term, Toda et al (2001) and Toda and Tsukimura (2004) found that there was a significant difference between the lateral-wedge insole with subtalar strapping group compared to the traditional insole group in reducing pain (p=0.004). Figure 2 below illustrates that the experimental group showed a greater effect at short-term in reducing pain.

Pain and function At short-term, Toda et al (2001) and Toda and Tsukimura (2004) found that there was no statistically significant difference between the lateral-wedge insole with strapping group and the traditional insole group in reducing pain and function (p=0.26). Figure 3 illustrates the differences between the intervention and control group over time (at short-, mid- and long-term) for pain and function. No statistically significant difference between the intervention group (lateral-wedge insoles) and the control group (traditional insoles) was found at short-, mid- and long-term.

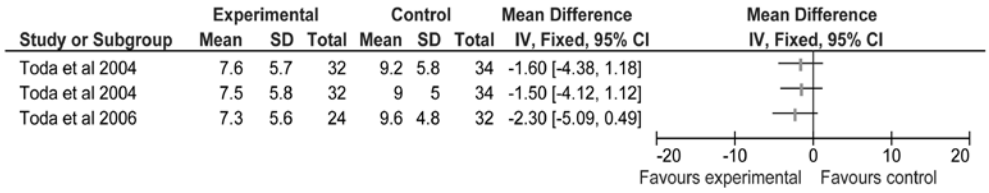
Femoral tibial angle (FTA) At short-term, Toda et al (2001) and Toda and Tsukimura (2004) found that there was an no statistically significant difference between the lateral- wedge insole with strapping group compared to the traditional insole group in improving the FTA (p=0.42) (Figure 4).

Figure 2: Pain at short-term



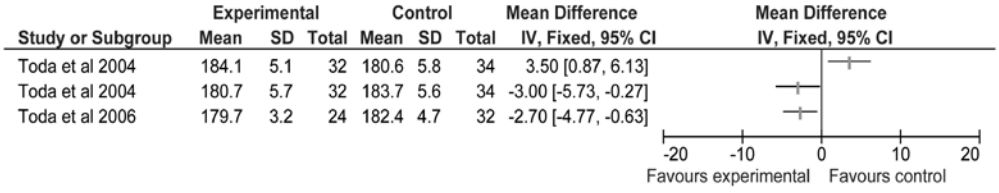
Key: Experimental=lateral wedged insole with subtalar strapping, Control=traditional shoe inserted wedged insole

Figure 3: Pain and function over time



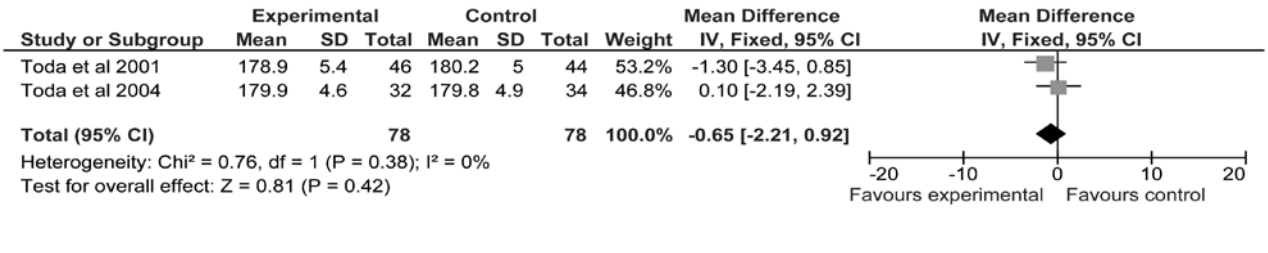
Key: s=short term, m=mid term, l=long term, Experimental=lateral wedged insole with subtalar strapping, Control=traditional shoe inserted wedged insole

Figure 4: FTA at short-term



Key: Experimental=lateral wedged insole with subtalar strapping, Control=traditional shoe inserted wedged insole

Figure 5: FTA over time



Key: s=short term, m=mid term, l=long term, Experimental=lateral wedged insole with subtalar strapping, Control=traditional shoe inserted wedged insole

Figure 5 illustrates the difference between the intervention and control group over time (at short-, mid- and long-term) for FTA. Although no statistically significant effect was found between the two groups at short-, mid- and long term, there seems to be a trend that at mid- and long-term, the intervention (lateral-wedge insole) group had a better outcome than the control group (traditional insole), when compared to the short-term. In the short-term it seems that the control group was favoured.

DISCUSSION

This is the first known meta-analysis comparing the effect of lateral-wedged insoles with subtalar strapping on reducing pain, and improving function and the FTA in adults with medial knee OA, compared to a traditional shoe inserted insole. The review found that lateral-wedge insoles with subtalar strapping significantly decreased pain in the short-term and seemed to have a positive effect on the FTA in the long-term, when compared to traditional insoles.

Patients who suffer from knee OA often complain of pain as being their main limiting factor during activities of daily living (ADLs). The fear of developing pain during activity restricts participation not only in their ADLs, but also in their community (Coleman et al 2008). According to Hopman-Rock et al (1997), chronic pain in the hip or knee negatively influences psychosocial well-being resulting in a decrease in quality of life. The fact that lateral-wedge insoles with subtalar strapping reduce pain in the short-term, could encourage patients to wear the insole for the recommended time period. This could further have an influence on the lateral-wedge insole with subtalar strapping positively changing the FTA and in the long-term, improving the patient's ability to function. Toda and Tsukimura (2006) found that the strapped insole group experienced a therapeutic effect during functional ambulation. The load on the medial compartment of the knee was not only reduced during the static phase of gait but during the dynamic phase as well. Toda and Segal (2002) also stated that an even distribution of load on the joint resulted in decreased pain with standing and ambulation. The combined effect of the reduction in pain, as well as an improved score on the Lequesne index indicates that the use of the lateral-wedge insole with subtalar strapping will improve the ability to perform ADL's and therefore have a further positive influence on the patient's quality of life.

At short-term, Toda et al (2001) and Toda and Tsukimura (2004) found that there was no statistically significant difference between the lateral-wedge insole with subtalar strapping group compared to the traditional insole group in improving the FTA. However, there seemed to be a trend that at mid- and long-term, the experimental (lateral-wedge insole) group tended to have a better outcome than the control group (traditional insole) (refer to table 5). Toda et al (2001) suggested that the use of the insole with subtalar strapping corrects not only the talar- and calcaneal malalignment, but also improves the FTA. A line drawn between the mid-femoral head to mid-ankle represents the load-bearing axis of the knee. In a knee with a varus deformity, the line passes medial to the knee and increases the force across the medial compartment of the knee (Sharma et al 2001). Therefore, the lateral-wedge insole with subtalar strapping fixates around the subtalar and ankle joints causing valgus angulation in the talus and the tibia which corrects the varus deformity of the lower limb. The insole without subtalar strapping does not correct lower limb alignment thus the effect of the insole alone is negated in the subtalar joint (Kuroyanagi et al 2007), with movement at the talus preventing correction of the valgus deformity at the FTA (Toda and Tsukimura 2004). Biomechanical structures require a longer time period to adapt to the correction and as a result a significant effect can only be seen in the long-term, which is what the results of this review suggest. In Toda and Tsukimura (2004) and Toda and Tsukimura (2006) the corrected FTA was maintained in both the mid- and the long-term, suggesting that there may have been a restriction in the progression of medial compartment knee OA for the strapped insole group. This further implicates that long-term wearing of the lateral-wedge insole will possibly limit progression of joint damage.

Clinically, the introduction of a lateral-wedge insole in the treatment of medial compartment knee OA provides healthcare workers with an additional form of intervention. Similar to the majority of conservative treatments for knee OA, the insoles may provide an alternative form of a low-cost, non-invasive intervention that may delay the need of more aggressive treatments (Crenshaw et al 1999). Taking into account the limitations and complications associated with invasive surgeries, such as a high tibial osteotomy, as well as the hesitancy shown by patients to undergo surgery, conservative treatment using the lateral-wedge insole with subtalar strapping would be more beneficial in the management of medial knee OA in some cases (Toda et al 2001). And even more economically beneficial in a third world setting like South Africa where low-cost interventions are needed due to the lack of resources. In addition, Kuroyanagi et al (2007) found that the reduction in the varus malalignment in the strapped insole group was similar to that of a high tibial osteotomy, which indicates that before surgery is considered for medial knee OA, conservative methods should be explored so as not to incur unnecessary costs and complications to the patient and the healthcare system budgets. Furthermore, the tibial osteotomy may not protect against the progression of medial knee OA, whereas there seems to be some evidence that the lateral-wedge insole with subtalar strapping may actually limit the progression of joint damage in the mid-and long-term (Toda et al 2001). Further advantages of wearing a lateral-wedged insole with subtalar strapping is that it does not slip or change position in shoes, possibly making it a more comfortable option and is also compatible with many types of shoes. It can also be worn barefoot, which cannot be easily achieved with other types of insoles.

Currently the conservative management for knee OA mainly consists of physiotherapy and medication. Physiotherapy aims to prevent, rehabilitate, educate, promote and refer if necessary. Evidence has shown physiotherapy OA interventions, such as manual therapy techniques, balance therapy, coordination, functional retraining techniques, knee taping, electrical stimulation and exercise programs, to be effective in reducing joint pain and stiffness, maintaining and improving joint mobility and limiting the progression of

medial knee OA (Fitzgerald and Oatis, 2004; Zhang et al 2008). Since lateral-wedge insole with subtalar strapping seems to limit the progression of the joint damage, it is recommended that lateral-wedged insole with subtalar strapping be used in conjunction with physiotherapy. The combination may result in a greater effect in treatment.

The high cost implications of OA for the healthcare system and the insufficient primary healthcare in South Africa, warrants less expensive and uncomplicated interventions. It is therefore crucial to promote self-management, especially in degenerative conditions like OA. Physiotherapists should thus recognize the importance of referral for orthotics of OA patients as an adjunctive self-management intervention. The lateral-wedge insole with subtalar strapping is an effective form of self-management that will provide relief of symptoms and improve quality of life, and make the patient feel in control of the situation (Toda and Tsukimura 2004).

The lateral-wedge insole may also be the most uncomplicated adjunctive treatment for OA patients to use at home. It is a simple intervention that, once it is made, is easily administered and can be managed by the patients themselves which should improve compliance. Coleman et al (2008) found that patients who suffer from chronic pain prefer to manage their own condition which not only improves the outcome of the condition but also reduces financial implications. Furthermore, the general OA population is usually elderly people who in South Africa are uneducated, making uncomplicated self-management interventions ideal. Lateral-wedge insoles could also possibly serve as an interim intervention since public hospitals in South Africa are overpopulated and often have long waiting periods for both physiotherapists and doctors especially in rural areas (http://www.doh.gov.za/docs/policy/quality_healthcare .pdf). The use of an insole is a once-off intervention which reduces the costs involved with treating chronic conditions. It therefore may be clinically, socially and financially advantageous to recommend management strategies such as orthoses for adults with medial knee OA that will encourage and enable them to actively participate in their own management and lessen the burden on the healthcare system and on healthcare workers.

However, there are a few limitations in the use of lateral-wedge insoles with subtalar strapping for medial knee OA patient. An increased rate of complications was reported in the experimental group with popliteal pain and lower back pain. A possible cause for these complications is the rapid reduction in FTA angle resulting in an acute imbalance from the surrounding muscles which have been compensating for the joint deformity (Toda et al 2001). The subjects in the study also complained of pain when walking on uneven ground while wearing the lateral-wedge insole with subtalar strapping. This could be due to the limited available movement in the subtalar joint resulting in increased loading of the knee (Toda and Segal 2002). Another drawback is that in order to wear the lateral-wedge insole with subtalar strapping in a shoe, a larger shoe size is required for it to fit comfortably (Toda and Tsukimura 2006).

Limitations of the included studies

The methodological quality of all three studies received a moderate PEDro rating. Allocation was not concealed, thus the investigators were aware of the group to which each subject had been assigned. Due to the nature of the intervention and control it was not possible to blind the subjects and therapists, but blinding of the assessor could have been applied. Since the assessors were not blinded in the included studies, a potential for observational bias was introduced into a study (Eccleston et al 2003). Intention to treat analysis was also not mentioned in any of the studies. Furthermore, publication bias may have been introduced as all the papers were published by the same authors. Another limitation was that all the participants were female and although males constitute a minority of the knee OA population, it would not be possible to apply the findings of these studies to males. All the studies were conducted in Japan therefore limiting the generalization of the results. In Toda and Tsukimura (2004) and Toda and Tsukimura (2006) there was no consistent control over the use of NSAID's therefore it is not possible to determine whether the effect was merely due to the use of the lateral-wedge insole with subtalar strapping. Another limitation was that the selection of outpatients in all three studies resulted in a bias toward inclusion of patients who could walk to a clinic, therefore were more likely to have mild knee OA. The studies did not clarify the duration of insole use each day.

CONCLUSION

The use of a lateral-wedge insole with subtalar strapping in the treatment of medial knee OA was statistically significant in reducing pain in the short-term with the FTA showing improvement in the mid- and long-term, when compared to a traditional insole. The long-term effects of the insole with subtalar strapping could limit the progression of medial knee OA, as it maintained the corrected FTA for periods of time. The lateral-wedge insole with subtalar strapping provides a financially feasible adjunctive self-management treatment for knee OA and should be considered before invasive procedures such as surgery.

Conflict of interest: None declared

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APPENDIX I:

PUBMED

1. Wedge* insole* AND subtalar strapping AND knee osteoarthritis
2. Lateral wedge* insole* AND subtalar strapping AND knee osteoarthritis
3. Lateral wedge* orthotic* AND subtalar strapping AND knee osteoarthritis
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