

# Clinical effects of lateral wedge arch support insoles in knee osteoarthritis

## A prospective double-blind randomized study

Ru-Lan Hsieh (MD)<sup>a,b,\*</sup>, Wen-Chung Lee (MD, PhD)<sup>c</sup>

### Abstract

We compared the short-term efficacy of rigid versus soft lateral wedge arch support (LWAS) insoles for patients with knee osteoarthritis (OA), as assessed using the International Classification of Functioning, Disability and Health (ICF) system, through a prospective, double-blind, randomized controlled trial.

Participants who fulfilled the combined radiographic and clinical criteria for knee OA, as defined by the American College of Rheumatology, were randomly prescribed 1 pair of rigid or soft LWAS insoles. Body functions and structures were evaluated according to Kellgren–Lawrence scores, the Foot Posture Index, Hospital Anxiety and Depression Scale scores, the pain–pressure threshold, postural stability, dynamic balance, and fall risk; activities and participation were assessed according to 10-m fast speed walking, stair climbing and chair rising times, and Chronic Pain Grade questionnaire responses; and knee OA-related health status was evaluated using the Knee Injury and Osteoarthritis Outcome Score (KOOS). Hospital Anxiety and Depression Scale scores, the pain–pressure threshold, physical activity, balance, Chronic Pain Grade questionnaire responses, and the KOOS were recorded before treatment and at 1-, 2-, and 3-month follow-ups.

We enrolled 90 participants, 70 women and 20 men, with mean ages of  $60.6 \pm 10.8$  and  $63.1 \pm 10.8$  years in the rigid and soft LWAS insole groups, respectively. Repeated-measures analysis of covariance revealed significant time  $\times$  group effect improvements in pain ( $P=0.008$  for the KOOS), stair ascent time ( $P=0.003$ ), daily living function ( $P=0.003$  for the KOOS), sports and recreation function ( $P=0.012$  for the KOOS), and quality of life ( $P=0.021$  for the KOOS) in the soft LWAS insole group.

Patients with knee OA who used soft LWAS insoles for a short term showed more significant improvement than did those who used rigid LWAS insoles in pain, physical activity, daily living function, sports and recreation function, and quality of life, which belong to the body functions and structures and the activities and participation components in the ICF scheme.

**Abbreviations:** ANCOVA = analysis of covariance, CI = confidence intervals, ICF = International Classification of Functioning, Disability and Health, KOOS = Knee Injury and Osteoarthritis Outcome Score, LWAS = lateral wedge arch support, OA = osteoarthritis.

**Keywords:** effect, insoles, knee, osteoarthritis

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## 1. Introduction

Osteoarthritis (OA) is the most common arthritic complaint among adults and a leading cause of chronic physical disability.<sup>[1]</sup> The prevalence of knee OA in the general population has ranged from 8.1% to 10% in previous studies.<sup>[2,3]</sup> Older women have a significantly higher prevalence of knee OA compared with older men.<sup>[4,5]</sup> Differences in endogenous sex hormones, body composition, knee structure and biomechanics, and psychosocial characteristics may play a role in the increased risk of knee OA in women.<sup>[6–8]</sup> Patients with knee OA experience pain, swelling, muscular atrophy, and restricted movement; these problems may negatively affect physical activity, causing difficulties in activities of daily living and reducing quality of life.<sup>[9]</sup>

The main treatment for knee OA entails controlling pain and avoiding potential complications of therapy.<sup>[10]</sup> OA is frequently associated with coronary artery disease, diabetes, obesity, and hypertension, and might be related to metabolic syndrome.<sup>[11]</sup> Patients with knee OA are likely to be older and may experience comorbidities; this patient group is at a relatively high risk of adverse gastrointestinal and cardiovascular effects of medication and polypharmacy.<sup>[12]</sup> Therefore, nonoperative treatments, such as shoe insoles, knee braces, and gait modification strategies, are commonly prescribed for patients with knee OA<sup>[13,14]</sup>; among them, insoles have become frequently used in recent years.<sup>[15–18]</sup>

In Taiwan, 49.5% to 51% of rehabilitation services at physical medicine and rehabilitation clinics are provided for musculoskeletal and soft tissue diseases,<sup>[19,20]</sup> and knee OA accounts for 4.6%.<sup>[20]</sup>

The increased external knee adduction moment throughout the stance phase of patients with knee OA increases their medial knee joint loading during gait. Lateral wedges shift the center of pressure laterally, reducing the external knee adduction moment and knee adduction angular impulses, alleviating pain, and improving function in patients with knee OA.<sup>[21,22]</sup> However, patients with knee OA exhibit more pronated feet than do healthy people.<sup>[23]</sup> Therefore, lateral wedge insoles may aggravate pronation and the ankle invertor moment.<sup>[24,25]</sup> An increased invertor moment may further increase the demand on those muscles, thus causing fatigue after prolonged use of the insoles.<sup>[26]</sup> The purposes of adding arch support to lateral wedge insoles are reducing ankle eversion and diminishing the ankle invertor moment.<sup>[26]</sup>

Although Abdallah et al reported that using lateral wedge arch support (LWAS) insoles did not immediately reduce the knee adduction moment significantly in patients with knee OA,<sup>[26]</sup> Yeh et al and Nakajima et al have demonstrated the immediate reduction of the peak external knee adduction moment and knee pain.<sup>[25,27]</sup> Our recent study demonstrated that rigid LWAS insoles maintain the subtalar joint in a neutral position, thus providing immediate improvement in physical activity and medium-term reduction in pain and improvement in physical activity and function.<sup>[28]</sup> However, because of the lack of a control group, we could not exclude the possibility that the improvement was caused by the natural recovery process.

The International Classification of Functioning, Disability and Health (ICF) describes functional health conditions from a biopsychosocial perspective.<sup>[29]</sup> Functional health status is reflected by the dynamic interaction of ICF components including body functions and structures, activities, participation, and personal and environmental factors.<sup>[30]</sup> Clinical investigations of the efficacy of OA therapies should include body functions and structures (e.g., pain, depression, and balance), and activities and participation (e.g., physical activity, activities of daily living, functional performance, and knee OA-related health status).

According to our research, no study has compared the efficacy of rigid LWAS insoles with that of soft LWAS insoles by applying ICF components to evaluate patients wearing self-selected comfortable shoes. The present study compared the short-term clinical efficacy of the 2 types of insoles for patients with knee OA by using the ICF system in a randomized, double-blind design. We hypothesized that the short-term use of both types of LWAS insoles would improve scores in measures of body functions and structures as well as activities and participation.

## 2. Methods

This was a prospective, randomized, double-blind clinical study examining patients with knee OA. Participants with confirmed diagnoses of bilateral knee OA were recruited from the clinic of the Department of Physical Medicine and Rehabilitation at a teaching hospital in Taipei, Taiwan. All participants fulfilled the combined radiographic and clinical criteria for knee OA, as defined by the American College of Rheumatology.<sup>[31]</sup> Specifically, patients with Kellgren–Lawrence scores of 2 or higher in the medial compartment, based on anteroposterior radiographic views of both knees while bearing weight, were recruited for this study. The participants ranged in age from 40 to 85 years. We

excluded patients with a self-reported history of malignancy, stroke, or knee implant operations and women who were pregnant or planned to become pregnant. The research was approved by the Institutional Review Board of Shin Kong Wu Ho-Su Memorial Hospital, and the study was performed in accordance with the World Medical Association Declaration of Helsinki. Informed consent was obtained from each participant. The trial was registered on ClinicalTrials.gov (registration number: NCT01765101; registration date: January 9, 2013) and conducted from January 2013 to December 2013.

### 2.1. Participant evaluation

Specific components of the ICF, namely, personal factors, body functions and structures (impairment), activities (limitations), and participation (restrictions), were evaluated as described herein.

### 2.2. Demographic data

Demographic data, namely, participant age, sex, education level, marital status, smoking and drinking habits, and comorbidities, were collected, and the body mass index was calculated.

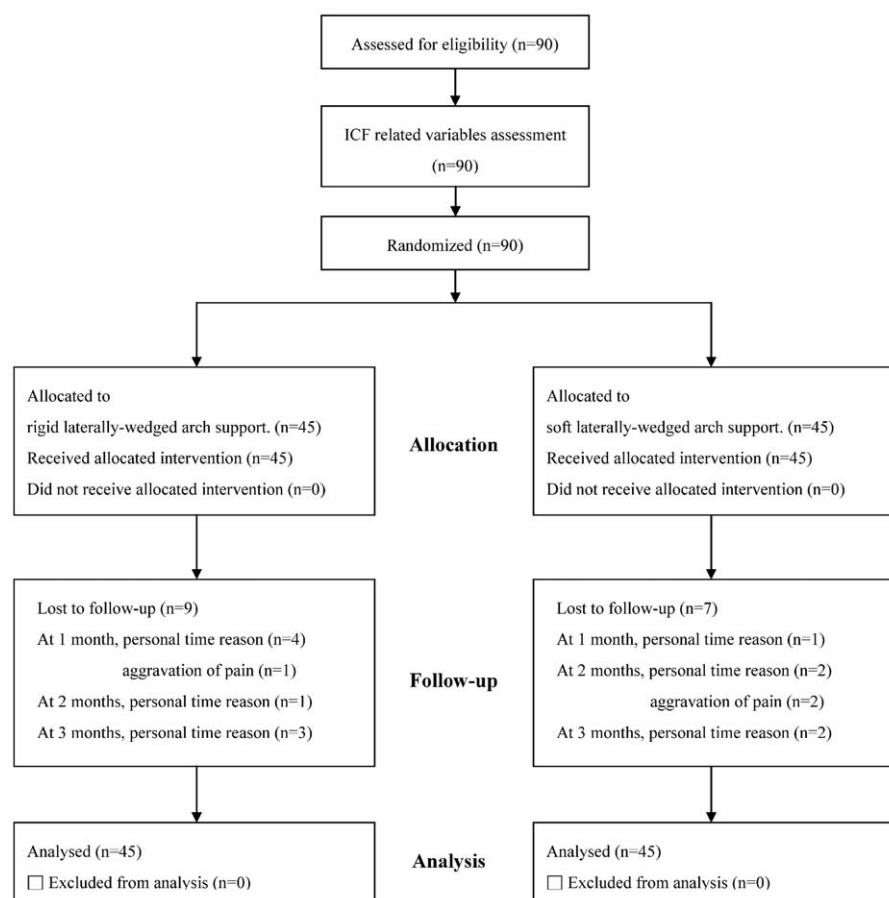
### 2.3. Body functions and structures

Foot posture was evaluated using the Foot Posture Index,<sup>[32]</sup> which is used to assess weight-bearing foot posture in a standing position according to a composite score of clinical observational criteria. Foot posture can be classified as follows: highly pronated (+10 to +12), pronated (+6 to +9), normal (0 to +5), supinated (−1 to −4), and highly supinated (−5 to −12). The index exhibited high intrarater reliability.<sup>[29]</sup>

Psychological distress was assessed using the Hospital Anxiety and Depression Scale.<sup>[33]</sup> Questions focused on feelings, states, and symptoms experienced during the preceding week. The scale comprises two 7-item subscales designed to measure anxiety and depression. A score exceeding 7 indicates the presence of anxiety and/or depression. The scale showed high reliability and validity.<sup>[34]</sup>

The pain–pressure threshold was measured using a pressure algometer, which was placed over the medial knee joint, 2 to 3 cm medial to the medial–lateral corner of the patella, with a contact area of 1 cm<sup>2</sup>. Pressure was increased at a rate of 1 kg/s after force was vertically applied. The pain–pressure threshold was obtained by calculating the mean of 3 series of pain–pressure threshold assessments. The pain–pressure threshold was defined as the level of stimulation at which the participant first experiences a painful sensation.<sup>[25]</sup> The system exhibited high validity and reliability.<sup>[35]</sup>

Postural stability, dynamic balance, and fall risk were assessed using the Biodex Stability System,<sup>[36]</sup> which consists of an unstable platform for testing a patient's postural control and balance. The system can provide the degree of tilt of the platform along both the medial–lateral and anterior–posterior axes; thus, an overall stability index can be obtained. Higher scores indicate greater postural variability and less stability in balancing on the platform.<sup>[37]</sup> The Biodex Stability System evaluates dynamic balance by measuring limits of stability, which are recorded while the participants use their bodies to move a cursor on a monitor screen from a central box to peripheral boxes that appear randomly. Higher scores indicate greater control of dynamic balance.<sup>[38]</sup> The risk of falling was measured through 6 rounds of



**Abbreviation: ICF, International of Functioning, Disability and Health.**

**Figure 1.** Flow diagram. ICF = International Classification of Functioning, Disability and Health.

tests with varying levels of resistance. Higher scores indicate a greater risk of falling compared with those of sex- and age-matched normal controls.<sup>[38]</sup> The system has good inter-rater and intrarater reliability.<sup>[39,40]</sup> For safety, the participants adopted a bipedal stance on the platform, with their eyes open and feet bare. The feet positions were recorded to ensure the same stance throughout all future test sessions. Each participant was allowed 1 practice attempt, followed by 1 formal test for each assessment.

#### 2.4. Activities and participation

Physical activity was measured through a 10-m walk test, a rising and sitting in a chair 5 times test, and a stair climb test. The tests were performed by asking participants to walk 10m as fast as possible, to stand up and sit down on a standard chair 5 times without using their hands as quickly as possible, and to ascend and descend a flight of stairs (14 steps, and each step measured 18 cm in height) in the shortest time possible. The time taken to complete the tests was measured in seconds. A longer completion time indicates a greater limitation on physical activity.

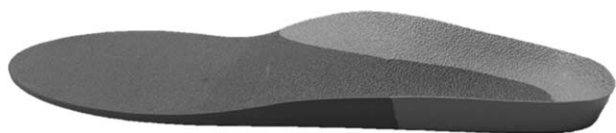
The Chronic Pain Grade questionnaire containing 7 items was used to measure 3 subscales: pain intensity score, disability score, and disability point.<sup>[41]</sup> A higher score indicates greater symptoms and more severe disability. We used the disability score and disability point to assess for disability in the present study.

#### 2.5. Knee OA-related health status

Participant perceptions of knee OA-related health status were assessed using the self-reported Knee Injury and Osteoarthritis Outcome Score (KOOS). A 5-point Likert scale was used to collect responses from the participants on 5 subscales: knee OA-related pain, other symptoms, daily living function, sports and recreation function, and knee-related quality of life.<sup>[42]</sup> Each scale ranges from 0 to 100, with 100 representing the least pain and dysfunction and 0 indicating the most pain and dysfunction. The system was reported to have high validity and reliability.<sup>[43]</sup>

#### 2.6. Block randomization

After basic data were recorded and the aforementioned examinations were performed, the participants were allocated to either the rigid or the flexible LWAS insole group (Fig. 1). The principle of block randomization was used to assign the participants to the groups, with the block size being 4. Allocation was initially concealed. Sealed envelopes, 1 for each participant with the designated treatment group listed inside, were selected randomly when the participants were recruited for the study. One physician enrolled all participants, and another investigator generated the allocation sequence and assigned the participants to their groups.



**Figure 2.** Insole with a rigid lateral wedge and arch support.

### 2.7. Intervention

Each participant in the rigid LWAS insole group received a pair of thermoplastic insoles molded specifically for him or her by a qualified physiatrist. The insoles consisted of a 5° lateral wedge with an arch support composed of high-density ethyl vinyl acetate (ICB Medical, Australia), and the subtalar joint was maintained in a neutral position (Fig. 2). The procedure was detailed in a previous study.<sup>[28]</sup>

Each participant in the soft LWAS insole group received a pair of ready-made insoles consisting of a soft 5° lateral wedge and an arch support composed of polyurethane (Lanew, Taiwan) (Fig. 3).

All participants were blinded to the type of insole prescribed and all interventions were provided by the same physiatrist. Both groups were instructed to wear the insoles inside self-selected comfortable shoes for 1 hour on the first day and thereafter increase their usage by 1 hour per day until they wore the insoles whenever they wore shoes.

### 2.8. Follow-up assessment

An investigator blinded to group allocation evaluated ICF-related variables at 4 consecutive time points: before treatment and after the participants had worn the insoles for 1, 2, and 3 months. Both the participants and the investigator were blinded to the insole status during the treatment and data collection periods. The KOOS pain score was used as the primary outcome.

### 2.9. Sample size

To detect an effect size of 0.77 at an  $\alpha$  level of 0.05 and power of 0.9, we had to evaluate at least 74 participants (37 participants for each group). Considering the possibility of 20% of the participants withdrawing during follow-up, we initially selected 90 participants (45 participants for each group).

### 2.10. Statistical analysis

The  $\chi^2$  or  $t$  test was used to analyze the data on demographics, body functions and structures, and activities and participation. The results are expressed as the mean  $\pm$  standard deviation and 95% confidence intervals (CI). Repeated-measures analysis of covariance (ANCOVA) was used to assess the ICF-related variables (e.g., psychological distress, pain, balance, physical activity, disability, and knee OA-related health status) during



**Figure 3.** Insole with a soft lateral wedge and arch support.

follow-up assessments, with the baseline measurements used as covariates. The group effect, time effect, and group  $\times$  time interaction effects for the 2 groups at the 3 postbaseline assessments were analyzed. The ANCOVA results are expressed as the  $F$  statistic, degrees of freedom, and  $P$  value. Intention-to-treat analysis (previous observation carried forward) was performed for all participants. The level of statistical significance was set at  $P < 0.05$ .

## 3. Results

We enrolled 90 participants, 70 women and 20 men, with mean ages of  $60.6 \pm 10.8$  and  $63.1 \pm 10.8$  years in the rigid and soft LWAS insole groups, respectively. Table 1 presents the participants' demographic data. In the rigid LWAS insole group, 4 participants withdrew because of limited personal time, and 1 participant withdrew because of subjective aggravation of pain at the 1-month follow-up. Because of limited personal time, 1 and 3 participants withdrew at the 2- and 3-month follow-ups, respectively. In the soft LWAS insole group, 1 participant withdrew because of limited personal time at the 1-month follow-up. Two participants withdrew because of aggravation of pain and 2 participants withdrew because of limited personal time at the 2-month follow-up, and 2 participants withdrew because of limited personal time at the 3-month follow-up. Thus, a total of 74 participants completed the study (36 and 38 participants in the rigid and soft LWAS insole groups, respectively). The dropout rates were 20% and 15.6% in the rigid and soft LWAS insole groups, respectively. No significant differences were evident in the demographics of the participants who completed the study and those who withdrew (data not shown).

The scores in each outcome measure at each time point for each group and the mean differences between groups based on 95% CI are summarized in Tables 2 and 3. No significant differences were found between the groups in baseline scores for psychological distress (anxiety and depression), the pain–pressure threshold, postural stability and balance, physical activity (10-m fast speed walking, stair climbing, and chair rising times), disability severity, or the pain, symptoms, daily living function, sports and recreation function, and quality of life subscales of the KOOS. Table 2 lists the results of repeated-measures ANCOVA for the short-term effects of variables related to body functions and structures, and Table 3 presents the variables related to activities and participation. Compared with the results of baseline assessments, statistically significant group  $\times$  time interaction improvements were noted in the soft LWAS group in pain ( $P=0.008$  for the KOOS), stair ascent time ( $P=0.003$ ), daily living function ( $P=0.003$  for the KOOS), sports and recreation function ( $P=0.012$  for the KOOS), and knee OA-related quality of life ( $P=0.021$  for the KOOS). Changes in the KOOS and stair ascent time of the 2 groups are shown in Fig. 4.

## 4. Discussion

This is the first study to apply the ICF system to patients with knee OA in a randomized, double-blind trial to compare the short-term clinical effects of wearing rigid and soft LWAS insoles. The use of soft LWAS insoles resulted in a significant short-term reduction in pain and improvements in stair ascent time, daily living function, sports and recreation function, and knee-related quality of life. The ICF system classifies these variables as belonging to the components of body functions and structures and activities and participation. In contrast to our assumption,



**Table 1****Basic demographics of participants.**

Variable	Rigid LWAS (n = 45)	Soft LWAS (n = 45)	P
Sex			0.379
Male	12 (26.7%)	8 (17.8%)	
Female	33 (73.3%)	37 (82.2%)	
Age	60.6 ± 10.8	63.1 ± 10.8	0.278
BMI, kg/m <sup>2</sup>	25.1 ± 2.3	25.4 ± 3.1	0.583
Marriage			
Yes	35 (77.7%)	34 (75.6%)	0.371
Education			0.096
Below ninth grade	14	24	
Above ninth grade	31	21	
Comorbidities			
Yes	32 (74.4%)	30 (69.8%)	0.492
Smoking			
Yes	3 (6.7%)	2 (4.4%)	0.305
Drinking			
Yes	8 (17.7%)	8 (17.7%)	0.283
Foot Posture Index			
Left	6.93 ± 1.92	7.00 ± 1.57	0.323
Right	7.00 ± 1.90	7.00 ± 1.37	0.401
Kellgren–Lawrence score			
Left	2.40 ± 0.50	2.00 ± 0.49	0.500
Right	2.38 ± 0.49	2.00 ± 0.49	0.415

The scores are presented as the number of cases (percentage) or the mean ± standard deviation for each variable. BMI = body mass index, LWAS = lateral wedge arch support.

the short-term use of rigid LWAS insoles did not improve the scores of ICF-related items.

Patients with knee OA typically experience pain and psychological distress (e.g., anxiety and depression).<sup>[44]</sup> Pain associated with knee OA may interfere with the ability to perform activities of daily living.<sup>[44,45]</sup> Poor performance in activities of daily living and sports and recreation function may exacerbate the disabilities of patients and increase their economic burden.<sup>[46]</sup> Our previous study showed that patients with knee OA scored lower in postural stability and quality of life measures than did age-matched controls.<sup>[9]</sup> The present study demonstrated that the short-term use of soft LWAS insoles could alleviate pain and improve physical activity, daily living function, sports and recreation function, and knee-related quality of life in patients with knee OA.

During the midstance phase of normal gait, an estimated 60% to 75% of a person's body weight is distributed over the medial knee joint.<sup>[47]</sup> Patients with knee OA exhibit a greater knee adduction moment when walking than do age-matched controls.<sup>[48]</sup> Wedge insoles can realign the foot in either the varus or the valgus plane from 5° to 10°.<sup>[23]</sup> Lateral wedge insoles alleviate pain by reducing the external knee adduction moment<sup>[16]</sup> and diminishing the medial knee joint load.<sup>[15]</sup> Lateral wedge insoles also may activate muscles and change the spatial position of the lower limb,<sup>[15]</sup> can retard foot supination and accentuate foot pronation, and may aggravate pronation in an already over-pronated ankle and foot.<sup>[23]</sup> Wedges might inhibit normal foot and ankle biomechanics, through mechanisms such as increasing the ankle invertor moment,<sup>[24]</sup> and thus exacerbate OA symptoms.<sup>[50]</sup>

Arch support insoles are commonly used clinically and improve foot alignment, shock attenuation, support, and stability during walking and running.<sup>[49,51,52]</sup> A 4% to 6% increase in the peak knee adduction moment during walking and running was observed in healthy young adults wearing arch support insoles.<sup>[51]</sup> However, no immediate change was reported in knee

pain, the adduction moment, or the adduction angular moment with the use of arch support insoles in athletic shoes by patients with knee OA.<sup>[53]</sup> Differences in ages, populations (healthy adults vs. patients with knee OA), and types of shoes might have affected the results of these studies.

LWAS insoles reduce the peak knee external adduction moment in patients with knee OA by laterally shifting the center of pressure to reduce the frontal plane ground reaction force and lever arm.<sup>[26]</sup> They also change the step width, progression angle, and valgus angle at the subtalar joint, enabling users to walk more naturally.<sup>[28]</sup> Although arches added to lateral wedge insoles are aimed at reducing ankle eversion, wearing LWAS insoles did not reduce the ankle invertor moment to a normal level in 1 study.<sup>[26]</sup> Previous studies have revealed that a larger angle in a lateral wedge insole increases the unloading force at the knee joint, causing greater ankle and foot discomfort.<sup>[16,54]</sup> Therefore, in this study, we provided the participants with insoles with a 5° lateral wedge and arch support.

People generally prefer wearing different shoes at various times, depending on personal preference and comfort. There are numerous shoe types, such as soft, lightweight, conventional walking, stability, and athletic shoes.<sup>[55]</sup> We allowed the participants to wear self-selected comfortable shoes in the present study. Soft shoes have the biomechanical advantages of barefoot walking, such as the absence of a lifted heel and stiff soles, and thus effectively reduce knee joint loads in patients with knee OA.<sup>[55]</sup> Soft insoles might have the same benefits as do soft shoes, thereby improving physical activity and knee OA-related health status, including pain, daily living function, sports and recreation function, and quality of life. Additional studies examining various insole and shoe type combinations are recommended.

Although our research represents a reasonable initial foray into the effects of LWAS insoles in patients with knee OA, we acknowledge that many factors, such as the rigidity of insoles, whether insoles are custom molded or ready-made, height of the

**Table 2****Body function scores.**

	Rigid LWAS (n=45)	Soft LWAS (n=45)	Mean difference (95% CI)	P	F test	Group (P)	Time (P)	Group × time (P)
HADS								
Anxiety								
T0	6.78 ± 3.95	7.73 ± 3.62	-0.95 (-2.57, 0.67)	0.247	F (3, 24)=1.4728	0.076	0.354	0.327
T1	6.05 ± 4.27	7.52 ± 3.87	-1.48 (-3.24, 0.29)	0.100	F (3, 24)=2.3274			
T2	5.98 ± 3.64	7.86 ± 3.82	-1.88 (-3.51, -0.25)	0.024	F (3, 24)=3.7641			
T3	6.84 ± 3.45	7.08 ± 3.25	-0.24 (-1.78, 1.30)	0.758	F (3, 24)=0.3946			
Depression								
T0	7.10 ± 2.92	8.00 ± 3.08	-0.90 (-2.21, 0.41)	0.174	F (3, 24)=1.8006	0.153	0.617	0.658
T1	6.90 ± 2.72	8.03 ± 2.73	-1.12 (-2.32, 0.08)	0.067	F (3, 24)=2.7176			
T2	6.83 ± 3.00	7.86 ± 3.06	-1.03 (-2.35, 0.30)	0.127	F (3, 24)=2.0984			
T3	7.08 ± 3.03	7.49 ± 3.17	-0.41 (-1.83, 1.02)	0.571	F (3, 24)=0.6832			
Pain—pressure threshold								
Left								
T0	2.55 ± 1.08	2.29 ± 1.06	0.26 (-0.19, 0.72)	0.252	F (3, 24)=1.4541	0.325	0.681	0.858
T1	2.18 ± 1.02	2.02 ± 0.76	0.16 (-0.22, 0.55)	0.410	F (3, 24)=0.9996			
T2	2.35 ± 0.74	2.08 ± 0.84	0.27 (-0.08, 0.62)	0.123	F (3, 24)=2.1289			
T3	2.54 ± 1.18	2.38 ± 1.05	0.16 (-0.36, 0.68)	0.548	F (3, 24)=0.7232			
Right								
T0	2.19 ± 1.07	2.28 ± 0.94	-0.09 (-0.51, 0.34)	0.682	F (3, 24)=0.5057	0.939	0.748	0.753
T1	2.38 ± 1.09	2.00 ± 0.81	0.38 (-0.03, 0.79)	0.072	F (3, 24)=2.6468			
T2	2.14 ± 0.72	2.25 ± 0.82	-0.11 (-0.45, 0.23)	0.537	F (3, 24)=0.7429			
T3	2.44 ± 1.10	2.26 ± 0.89	0.18 (-0.28, 0.64)	0.439	F (3, 24)=0.9352			
Biodex Stability System								
Postural stability								
T0	0.57 ± 0.25	0.75 ± 0.42	-0.18 (-0.33, -0.03)	0.015	F (3, 24)=4.2686	0.097	0.996	0.712
T1	0.73 ± 0.36	0.84 ± 0.51	-0.11 (-0.30, 0.08)	0.240	F (3, 24)=1.4996			
T2	0.66 ± 0.30	0.92 ± 0.84	-0.26 (-0.54, 0.02)	0.069	F (3, 24)=2.6887			
T3	0.63 ± 0.35	0.68 ± 0.40	-0.05 (-0.22, 0.13)	0.599	F (3, 24)=0.6362			
Limits of stability								
T0	45.69 ± 11.65	48.46 ± 10.82	-2.77 (-7.53, 2.00)	0.251	F (3, 24)=1.4578	0.744	0.672	0.341
T1	46.81 ± 13.24	47.91 ± 13.42	-1.10 (-6.82, 4.62)	0.703	F (3, 24)=0.4744			
T2	45.25 ± 12.94	50.07 ± 13.86	-4.82 (-10.76, 1.11)	0.109	F (3, 24)=2.2445			
T3	44.18 ± 13.97	49.97 ± 11.73	-5.79 (-11.78, 0.21)	0.058	F (3, 24)=2.8605			
Fall risk								
T0	2.45 ± 2.04	2.91 ± 1.53	-0.46 (-1.23, 0.30)	0.230	F (3, 24)=1.5393	0.368	0.343	0.962
T1	2.19 ± 1.76	2.35 ± 1.52	-0.16 (-0.86, 0.55)	0.653	F (3, 24)=0.5500			
T2	1.90 ± 1.00	2.52 ± 1.75	-0.61 (-1.25, 0.02)	0.057	F (3, 24)=2.8778			
T3	2.24 ± 1.65	2.62 ± 1.91	-0.38 (-1.21, 0.45)	0.363	F (3, 24)=1.1138			
KOOS								
Pain								
T0	40.94 ± 16.38	37.27 ± 17.27	3.67 (-3.55, 10.90)	0.315	F (3, 24)=1.2462	0.049*	<0.001†	0.008†
T1	41.10 ± 13.64	38.20 ± 15.77	2.91 (-3.43, 9.24)	0.364	F (3, 24)=1.1112			
T2	42.89 ± 15.75	42.83 ± 14.91	0.06 (-6.68, 6.80)	0.987	F (3, 24)=0.0450			
T3	41.55 ± 17.57	47.68 ± 14.42	-6.13 (-13.48, 1.22)	0.101	F (3, 24)=2.3178			
Symptoms								
T0	37.47 ± 16.83	39.35 ± 18.58	-1.88 (-9.49, 5.74)	0.625	F (3, 24)=0.5940	0.900	0.265	0.343
T1	35.74 ± 15.11	37.52 ± 16.47	-1.78 (-8.57, 5.01)	0.604	F (3, 24)=0.6280			
T2	36.98 ± 17.18	39.26 ± 17.43	-2.28 (-9.89, 5.33)	0.553	F (3, 24)=0.7144			
T3	36.23 ± 15.48	41.54 ± 15.05	-5.31 (-12.29, 1.67)	0.134	F (3, 24)=2.0474			

Scores are expressed as the mean ± standard deviation. We report the *F* statistic from a repeated-measures ANCOVA as  $F(df_{\text{time}}, df_{\text{error}}) = F$  test. ANCOVA = analysis of covariance, CI = confidence interval; HADS = Hospital Anxiety and Depression Scale, KOOS = Knee Injury and Osteoarthritis Outcome Score, LWAS = lateral wedge arch support, T0 = time point before treatment, T1 = time point after 1 month of treatment, T2 = time point after 2 months of treatment, T3 = time point after 3 months of treatment.

\*  $P < 0.05$ .

†  $P < 0.01$ .

medial arch, angle of the lateral wedge, insole construction, usage duration, shoe type, and age factors, affect the results. Therefore, the long-term effects of different types of insoles in patients with knee OA require further investigation.

The main strength of this study was its use of reliable and patient-centered objective and subjective measurements based on

the ICF model and recorded using a double-blind, randomized design. The ICF model provides clinicians with knowledge on specific components relevant to the observed therapeutic effects of the LWAS insoles.

This study was subject to several limitations. First, we did not evaluate the biomechanical effects of the insoles; this topic warrants

**Table 3****Activities and participation of participants.**

	Rigid LWAS (n=45)	Soft LWAS (n=45)	Mean difference (95% CI)	P	F test	Group (P)	Time (P)	Group × time (P)
Physical activity								
10-m fast walking						0.039*	0.003 <sup>†</sup>	0.213
T0	8.36±2.58	9.29±2.96	-0.93 (-2.11, 0.25)	0.121	F (3, 24)=2.1446			
T1	7.96±1.73	8.76±2.39	-0.80 (-1.70, 0.10)	0.078	F (3, 24)=2.5685			
T2	7.97±1.45	8.61±2.12	-0.64 (-1.45, 0.16)	0.116	F (3, 24)=2.1849			
T3	8.03±1.43	8.39±2.22	-0.36 (-1.21, 0.50)	0.408	F (3, 24)=1.0042			
Stair ascent time						<0.001 <sup>†</sup>	<0.001 <sup>†</sup>	0.003 <sup>†</sup>
T0	11.07±2.60	14.56±7.43	-3.49 (-5.89, -1.09)	0.004	F (3, 24)=5.7861			
T1	10.77±2.83	13.14±5.04	-2.37 (-4.16, -0.59)	0.009	F (3, 24)=4.8371			
T2	10.80±2.54	12.44±4.24	-1.64 (-3.19, -0.09)	0.037	F (3, 24)=3.3141			
T3	10.76±3.30	11.65±4.25	-0.89 (-2.63, 0.85)	0.373	F (3, 24)=1.0884			
Stair descent time						0.003 <sup>†</sup>	0.001 <sup>†</sup>	0.058
T0	10.69±3.51	13.60±6.14	-2.91 (-5.06, -0.77)	0.007	F (3, 24)=5.1249			
T1	10.20±3.15	12.36±5.40	-2.16 (-4.08, -0.23)	0.026	F (3, 24)=3.6799			
T2	10.28±3.22	12.54±5.81	-2.27 (-4.35, -0.18)	0.033	F (3, 24)=3.3417			
T3	10.16±3.00	10.95±4.07	-0.79 (-2.42, -0.85)	0.341	F (3, 24)=1.1722			
Chair rising time						0.278	<0.001 <sup>†</sup>	0.954
T0	16.39±4.86	17.73±6.18	-1.34 (-3.72, 1.03)	0.263	F (3, 24)=1.4143			
T1	15.58±4.95	17.03±5.70	-1.45 (-3.75, 0.84)	0.211	F (3, 24)=1.6199			
T2	15.34±4.32	16.18±5.13	-0.84 (-2.95, 1.26)	0.426	F (3, 24)=0.9636			
T3	14.36±3.65	15.55±6.42	-1.19 (-3.58, 1.21)	0.326	F (3, 24)=1.2142			
Chronic Pain Grade questionnaire								
Disability score						0.576	0.089	0.879
T0	38.65±21.75	40.59±24.60	-1.94 (-11.87, 7.99)	0.698	F (3, 24)=0.4818			
T1	33.82±21.57	38.94±23.15	-5.12 (-14.79, 4.55)	0.296	F (3, 24)=1.3042			
T2	35.58±20.64	40.41±22.68	-4.82 (-14.42, 4.77)	0.320	F (3, 24)=1.2315			
T3	29.72±16.72	32.11±23.11	-2.38 (-11.78, 7.01)	0.615	F (3, 24)=0.6101			
Disability points						0.465	0.117	0.817
T0	3.91±2.35	4.13±2.56	-0.22 (-1.26, 0.82)	0.687	F (3, 24)=0.4982			
T1	3.38±2.23	4.30±2.26	-0.91 (-1.87, 0.03)	0.075	F (3, 24)=2.6068			
T2	3.44±2.08	4.22±2.34	-0.78 (-1.71, 0.15)	0.134	F (3, 24)=2.0474			
T3	2.98±1.76	3.38±2.30	-0.40 (-1.26, 0.46)	0.436	F (3, 24)=0.9417			
KOOS								
Daily living function						0.007 <sup>†</sup>	<0.001 <sup>†</sup>	0.003 <sup>†</sup>
T0	45.01±14.20	38.01±17.00	7.01 (0.31, 13.71)	0.041	F (3, 24)=3.2093			
T1	44.54±14.06	40.85±14.34	3.70 (-2.40, 9.79)	0.231	F (3, 24)=1.5353			
T2	47.47±16.24	44.56±14.27	2.90 (-3.82, 9.62)	0.393	F (3, 24)=1.0394			
T3	44.80±16.30	47.99±14.44	-3.19 (-10.28, 3.91)	0.374	F (3, 24)=1.0859			
Sports and recreation function						0.033	<0.001 <sup>†</sup>	0.012 <sup>*</sup>
T0	21.22±26.87	14.03±23.63	7.19 (-3.64, 18.02)	0.190	F (3, 24)=1.7180			
T1	23.72±25.11	16.09±22.31	7.64 (-2.61, 17.88)	0.142	F (3, 24)=1.9924			
T2	21.56±22.47	26.18±21.89	-4.62 (-14.43, 5.19)	0.352	F (3, 24)=1.1426			
T3	23.07±23.73	27.84±20.77	-4.77 (-15.04, 5.51)	0.358	F (3, 24)=1.1268			
Quality of life						0.266	<0.001 <sup>†</sup>	0.021 <sup>*</sup>
T0	19.92±19.22	19.12±18.45	0.80 (-7.28, 8.88)	0.845	F (3, 24)=0.2719			
T1	22.37±22.47	20.22±19.87	2.15 (-6.93, 11.24)	0.639	F (3, 24)=0.5718			
T2	21.61±22.07	26.47±18.90	-4.86 (-13.94, 4.22)	0.290	F (3, 24)=1.3233			
T3	24.62±20.89	32.60±17.65	-7.99 (-16.90, 0.93)	0.078	F (3, 24)=2.5685			

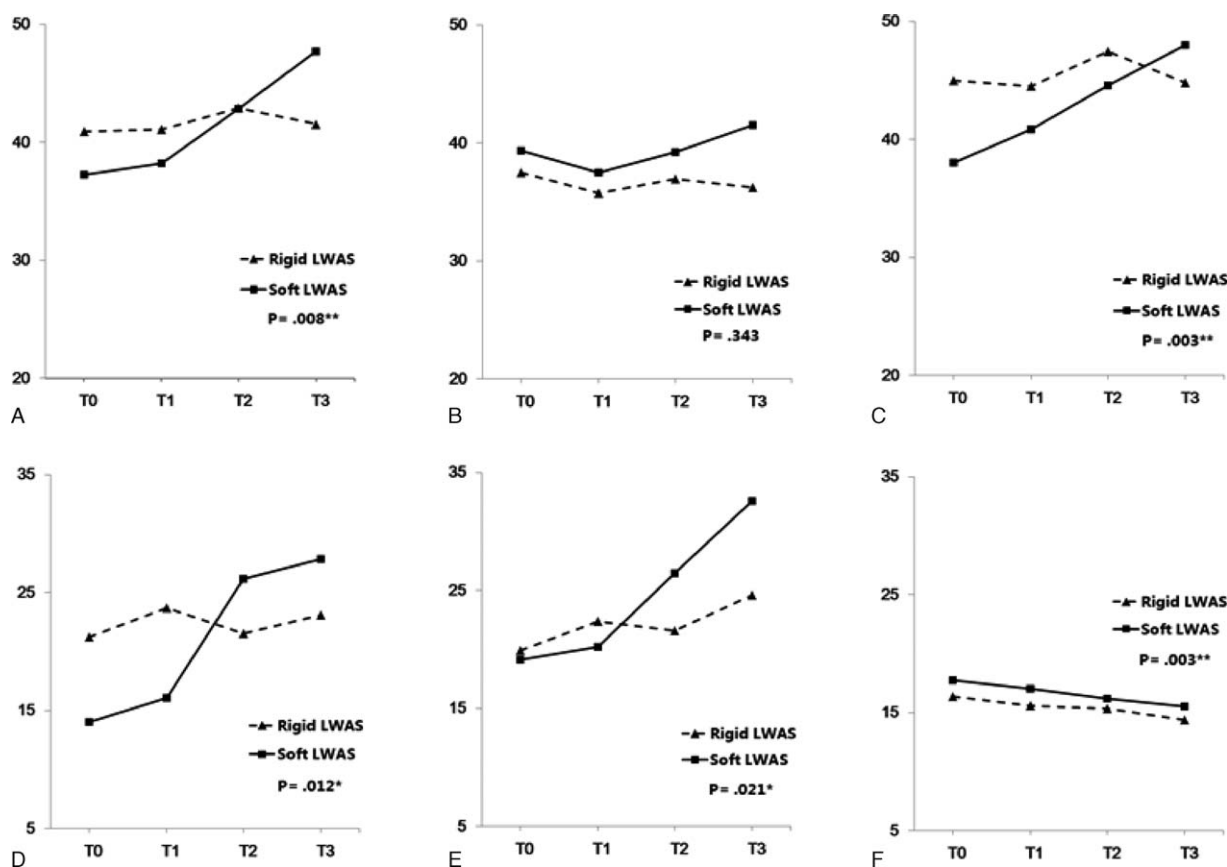
Scores are expressed as the mean ± standard deviation. We report the *F* statistic from a repeated-measures ANCOVA as  $F(df_{\text{time}}, df_{\text{error}}) = F$  test. ANCOVA = analysis of covariance, CI = confidence interval, KOOS = Knee Injury and Osteoarthritis Outcome Score, LWAS = lateral wedge arch support, T0 = time point before treatment, T1 = time point after 1 month of treatment, T2 = time point after 2 months of treatment, T3 = time point after 3 months of treatment

\*  $P < 0.05$ .

<sup>†</sup>  $P < 0.01$ .

further investigation. Second, we followed the participants for only 3 months; whether the observed short-term benefits of the soft LWAS insoles continue after prolonged use is unclear. Third, factors such as insole construction, arch support height, lateral wedge angle, and shoe type might affect the study results. Long-term follow-up studies comparing different types of insoles and shoes are warranted. Finally,

the total number of patients (90) was not high, with 78% being women, and 17.8% of dropout rate. Therefore, our study provides only preliminary but valuable data that should be validated in a larger study. Future studies should have a larger sample size and use a community-based sample to confirm the generalizability of our results.



**Figure 4.** Changes in KOOS and stair ascent time. Triangles and squares represent the rigid and flexible LWAS insole groups, respectively. (A) KOOS pain subscale; (B) KOOS other symptoms subscale; (C) KOOS daily living function subscale; (D) KOOS sports and recreation function subscale; (E) KOOS knee-related quality of life subscale; and (F) stair ascent time. KOOS = Knee Injury and Osteoarthritis Outcome Score, LWAS = lateral wedge arch support, T0 = time point before treatment, T1 = time point after 1 month of treatment, T2 = time point after 2 months of treatment, T3 = time point after 3 months of treatment. Group  $\times$  time interaction effects: (\*)  $P < 0.05$ ; (\*\*)  $P < 0.01$ .

## 5. Conclusions

Patients with knee OA who received short-term therapy with soft LWAS insoles experienced significant pain alleviation and improvements in physical activity, daily living function, sports and recreation function, and quality of life. These variables are classified in the body functions and structures and the activities and participation components in the ICF scheme. Additional clinical trials evaluating the biomechanical effects and the long-term efficacy of different types of insoles in patients with knee OA are necessary.

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