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Original Article

Effects of a Lateral Wedged Insole in Patients with Medial Compartment Osteoarthritis of the Knee

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Background: Medial compartment osteoarthritis (OA) of the knee is one of the most prevalent and disabling chronic conditions affecting older adults. This study assesses the efficacy of an inserted lateral wedged insole for the conservative treatment of medial compartment knee OA.
Methods: Thirteen outpatients (9 females and 4 males with a mean age of 71.0 and a standard deviation of 5.5) with medial compartment knee OA were prospectively treated with an inserted lateral wedged insole with an elevation of 12 mm for three months. The baseline and three-month visual analog scale (VAS) scores for subjective knee pain and the remission score of the Lequesne index of severity for knee OA were compared. Standing radiographs with and without insoles were also used to analyze the femorotibial, talocalcaneal, and talar tilt angles at the baseline and at the final assessment.
Results: Participants wearing the inserted lateral wedged insole showed a significant improvement in their VAS pain scores and remission scores in the Lequesne index ($P<0.0001$). However, these statistically significant differences were not found in all angles when compared with values at the baseline, immediate, and three-month assessments.
Conclusions: The inserted lateral wedged insole induced a symptomatic relief in patients with medial compartment knee OA, but it did not significantly improve the radiographs taken in the static position. The therapeutic effect should be further evaluated during the static and dynamic phases using a motion analysis system, as well as force plates to determine the kinematic and kinetic effects of the treatment. Hence, a longer-term clinical follow up should also be considered in future studies. (Tw J Phys Med Rehabil 2007; 35(4): 197 - 205)

Key Words: insole, lateral wedged, knee osteoarthritis, orthotic device, radiography

INTRODUCTION

Osteoarthritis (OA)[1] of the knee is one of the most prevalent and disabling chronic conditions affecting older

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adults. Pain in the knees and limitation of motion restrict the independence of elders by impairing their performance of activities of daily living such as climbing stairs, getting in and out of chairs, and walking long distances. In epidemiological studies, people who require repetitive knee bending and high physical demand in their occupations show higher rates of subsequent radiographic knee OA than those with less physically demanding occupations.[2,3]

The diagnosis of knee OA is based primarily on its history and physical examination, but radiographic findings, including asymmetric joint space narrowing, subchondral sclerosis, osteophyte formation, subluxation, and distribution patterns of osteoarthritic changes, can be helpful in making a diagnosis. The following three joint compartments combine to form the knee: the lateral tibiofemoral compartment, the medial tibiofemoral compartment, and the patellofemoral compartment. Patients with knee OA usually manifest a major involvement in only one compartment, for which the medial compartment is involved nearly 10 times more frequently than the lateral compartment.[4] Many investigators have previously reported a variety of risk factors for knee OA, and knee alignment has been thought to play an important role in these factors. Sharma and colleagues[5] concluded that varus alignment was associated with a fourfold increase in the odds of medial progression; and for valgus alignment, almost a fivefold increase in the odds of lateral progression. The severity of malalignment correlated with the magnitude of joint space loss and the burden of malalignment predicted the deterioration in physical function.

The treatment of knee OA[6,7] involves alleviating pain, attempting to rectify mechanical malalignment, and identifying and addressing manifestations of joint instability. Pharmacologic therapies including non-steroidal anti-inflammatory drugs (NSAID), intra-articular corticosteroid injections, glucosamine and chondroitin sulfate, and injections of hyaluronic acid may be prescribed for patients with knee OA. Some are advised to receive physical therapy for pain relief, perform exercises to strengthen the quadriceps, and use a knee sleeve or brace with a walking aid as nonpharmacologic treatment methods. For patients with severe knee OA, surgical intervention, such as total knee arthroplasty or high tibial osteotomy, are advised.[8]

A conservative therapy, such as the use of an insole that provides a low cost, effective complement or alternative to surgical treatment, could be a very useful adjunct to the care of these patients. Likewise, this treatment could benefit the healthcare economy. One of the first forms of mechanical therapy developed for patients with medial compartment knee OA was the lateral wedged orthosis which was popularized in Japan in the early 1980s.[9,10] The purpose of the lateral wedged insole is to alter the mechanical alignment of the lower leg by enhancing a valgus correction of the calcaneus. Yasuda and Sasaki[10] characterized the mechanism of action of the inserted insole as a reduction of the medial knee joint surface loading with a concurrent reduction in lateral tensile forces.

Although the lateral wedged insoles prescribed for OA knee patients are common in Japan and account for a significant improvement in subtalar strapping lateral wedged insoles, relatively few studies have been conducted in the Chinese context, and only a few experiments for such orthotic devices in medial compartment OA knees have been conducted. Therefore, our study was designed to assess symptomatic relief, remission score on the Lequesne index, and radiographic change of knee OA in patients treated with an inserted lateral wedged insole.

MATERIALS AND METHODS

This study prospectively evaluated patients with knee OA who were treated with an inserted lateral wedged insole with an elevation of 12 mm based on Toda and colleagues' conclusion.[11] They found that the 16-mm laterally wedged insoles with subtalar strapping had a significantly greater valgus correction of the femorotibial angle than the 8-mm lateral wedged insoles. The remission score was significantly improved in the 12-mm group compared with the 16-mm group, but adverse effects were more common in the 16-mm group than in the 12-mm or 8-mm groups. The principal outcome measurements considered were the visual analog scale (VAS) score, the remission score on the Lequesne index, and the radiographic assessments of bony alignment. The protocol for this study was approved by the Institutional Review Board of the China Medical University Hospital, Taichung, Taiwan.

After signing the consent form, 13 outpatients (9 females and 4 males with a mean age of 71.0 and a standard deviation of 5.5) seen in our physical medicine and rehabilitation department from September to December 2005 were enrolled. All of them were diagnosed as having medial compartment knee OA, according to the criteria set by the American College of Rheumatology. Patients were excluded if they had a history of rheumatoid arthritis, gouty arthritis, congenital foot problems and deformity, and fracture or operation on the lower limbs; if they were suffering from a limitation of range of motion of the hip and ankle joints; if they had any significant peripheral or central nervous system disease such as Parkinson's disease, Alzheimer's disease, or multiple sclerosis; that is, they cannot walk independently; or if they cannot understand and complete whole research courses. In the beginning of the study design, participants were informed that they will be orally treated with a NSAID (meloxicam, 7.5 mg) twice a day as adjunctive therapy in case of severe knee pain, and they were required to quit physical therapy during this clinical research period. Fortunately, none of the 13 patients had to use NSAID before and during the whole study period due to severe knee pain.

The age, height, weight, and active and passive range of motion (ROM) in the bilateral knee joints, the VAS score for knee pain, the Lequesne index of severity for knee OA, and the Kellgren-Laerence (K-L) grade for the stage and degree of bone destruction were evaluated at the baseline. Height was measured to the nearest 1 cm using a stadiometer and weight was measured to the nearest 0.1 kg while the subjects stood erect. Body mass index (BMI) was calculated using weight and height measurements (kg/m^2). In addition, the range of motion for knee joints was measured to 1 degree by a goniometer.

The subjects were then requested to describe the pain intensity in their knees. Pain intensity was assessed using the Visual Analog Pain Scale, a card with an uncalibrated scale ranging from 0 to 100 on one side (with 0 representing no pain and 100 representing the worst imaginable pain) and a corresponding 100-mm ruler on the other side (with each millimeter representing one pain level). They were asked to subjectively estimate their pain level by moving the pointing device along the uncalibrated scale between 0 to 100. Through this method the exact value of pain intensity can be obtained by referring the uncalibrated scale to the ruler on the back side (measured to the nearest 1 mm). Each symptom relating to knee OA was evaluated according to the Lequesne index.[12,13]

To adequately assess the changes in ankle and knee joints, the antero-posterior (AP) views should be obtained while a patient is in a standing position. Radiographs were evaluated for changes in the characteristics of knee OA in the AP views using the Kellgren and Lawrence grade, as described in the Atlas of Standard Radiographs.[14] The femorotibial angle (Figure 1-A)[10] was formed by a pair of parallel lines drawn through the distal one-third of the femur and the proximal one-third of the tibia. The talocalcaneal angle (Figure 1-B) was formed by the line connecting the medial and lateral convex ends of the trochanter talus to the distal ends of the malleoli and a line parallel to the floor, passing through 2.5 cm distal to the lateral malleolus and connecting the distal ends of the malleoli. Finally, the talus tilt angle (Figure 1-C) was formed by a line parallel to the floor and the tilt of the trochanter talus.[15]

The insole, which consisted of a lateral wedge with an elevation of 12 mm (Figure 2-A, B, C, D), was inserted into ordinary shoes. It was wrapped and fixed with an adhesive elastic bandage while standing radiographs of the knee and ankle joints were taken. Each participant was instructed to use the insole within their shoes, attached by a Velcro strap at the bottom, without an ankle brace while at home for a period of three to six hours each day. The trial lasted for three months; after which the baseline and three-month VAS scores for subjective knee pain and the remission scores of the Lequesne index of severity for knee OA were compared. Standing radiographs with and without insoles were used to analyze the femorotibial, talocalcaneal, and talar tilt angles at the baseline and for final assessments.

STATISTICAL ANALYSIS

The baseline values for age, height, weight, BMI, and active and passive range of motion of bilateral knee joints are summarized in Table 1. Student's paired *t* test was used to determine significant differences between the baseline and three-month assessment for the VAS score and the remission score of the Lequesne index. A one-way analysis of variance was used to assess the statistical significances in radiographic assessments among the baseline, immediate, and three-month assessments. P values less than 0.05 were considered significant.

RESULTS

Participant Characteristics

A total of 13 participants completed the study and returned for the final follow-up visit. Table 1 shows their age, height, weight, BMI, knee joint ROM, baseline VAS score, and Lequesne index at the initial assessment. Through a visual inspection of the used insole and as recorded in the diary by the participants themselves, we concluded that each participant had used the insole as instructed.

Radiographic Assessments

In this study, the distribution of Radiographic (Kellgren–Lawrence) grade of knees in the thirteen cases is Grade 2 – 1, Grade 3 – 8, and Grade 4 – 4. A comparison of radiographic angles among the baseline (without insole), immediate (with insole), and three-month (without insole) assessments is shown in Table 2. These statistically significant differences were not found in the femorotibial, the talocalcaneal, and the talus tilt angles of both knees.

Clinical Assessments

Table 3 shows a comparison of the baseline assessment with the final assessment in VAS score and remission score of the Lequesne index. Compared with the initial assessment, the remission score on the Lequesne index at the final assessment showed a greater improvement (10.08 ± 1.67 and 6.92 ± 1.58, respectively), and the paired *t*-test showed a statistically significant value ($P<0.0001$). Moreover, the VAS scores were significantly different between the baseline (53.62 ± 10.66) and the three-month assessment (38.77 ± 10.73) ($P<0.0001$).

DISCUSSION

The improved VAS score and remission score of the Lequesne index still demonstrated the beneficial effect of orthotics devices in the management of medial compartment knee OA, even if this study failed to demonstrate relevant radiographic changes after the insertion of the lateral wedged insole. This result corroborates the conclusion in the study of Pham and colleagues,[16] where no structural effect of laterally wedged insoles was noted.

Yasuda and Sasaki[10] speculated that the beneficial effect of the inserted lateral wedged insole was due to the reduction in the medial knee joint surface loading, even though the orthotic device failed to correct the femorotibial angle in the varus deformity knee OA. Yoshitaka Toda and colleagues[11,13,15,17-19] performed a series of studies and concluded that the subtalar strapping insole resulted in a significant change in the femorotibial, the talocalcaneal, and the talus tilt angles, while the inserted insole alone produced a significant change only in the talocalcaneal angle on standing full-length radiographs. This apparent lack of radiographic change is in contradiction with Toda's previous studies suggesting the efficacy of lateral wedged insoles in patients with medial knee OA. Three main reasons could explain this discrepancy: first, the method with which the insole is applied; second, the age and severity of the participants' knee OA; and third, the evaluation tools used for assessment.

Let us consider the first reason. There are many methods in applying the lateral wedged insole, including subtalar strapping support, sock-type ankle support, and direct insertion into ordinary shoes. Most Japanese workers wear shoes outdoors but not inside their office, making the inserted insole of no use when participants are at work. Nearly all Japanese housewives spend most of the day inside their homes without footwear, so most patients in Japanese studies used the insoles without footwear. Toda suggested that the movement of the talus may prevent calcaneal valgus correction, thereby preventing femoratibial valgus correction while using the inserted insole.[17] Meanwhile, most older adults in Taiwan have the habit of wearing ordinary shoes or slippers; hence, subtalar strapped insoles are not suitable for them. This is the reason why we still chose the inserted insole for our studies. However, in contrast to other studies, we designed the insole with a medial foot arch so as to maintain the natural foot alignment. Thus, a new style of lateral wedged insole with a different mechanism may be used in future studies.

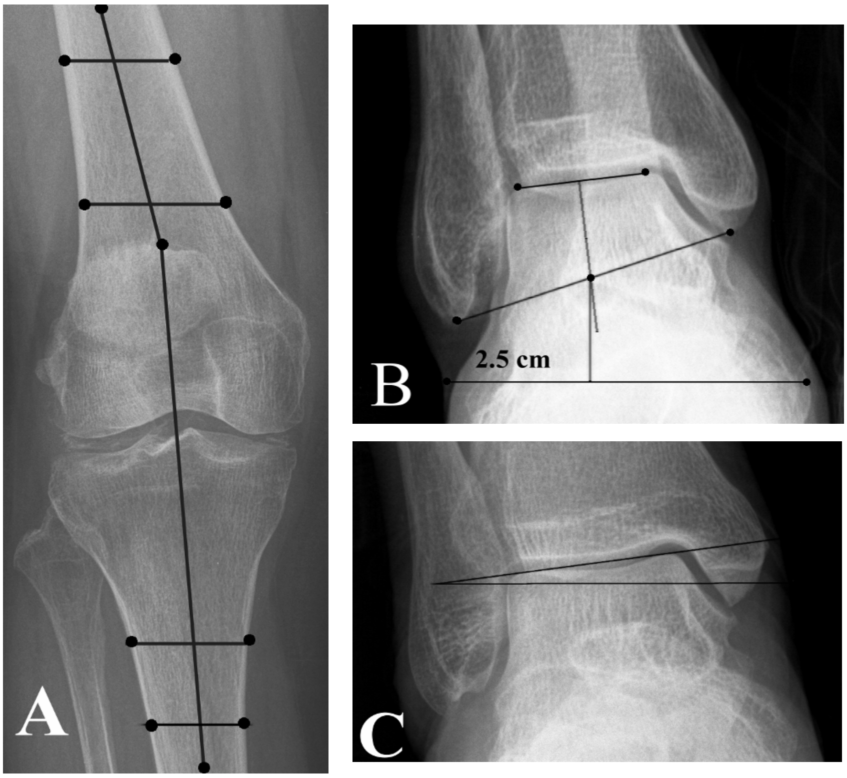

Figure 1. Radiographic analysis. A. The femorotibial angle was formed by a pair of parallel lines drawn through the distal one-third of the femur and the proximal one-third of the tibia. B. The talocalcaneal angle was formed by the line connecting the medial and lateral convex ends of the trochanter talus to the distal ends of the malleoli and a line parallel to the floor, passing through 2.5 cm distal to the lateral malleolus and connecting the distal ends of the malleoli. C. The talus tilt angle was formed by a line parallel to the floor and the tilt of the trochanter talus

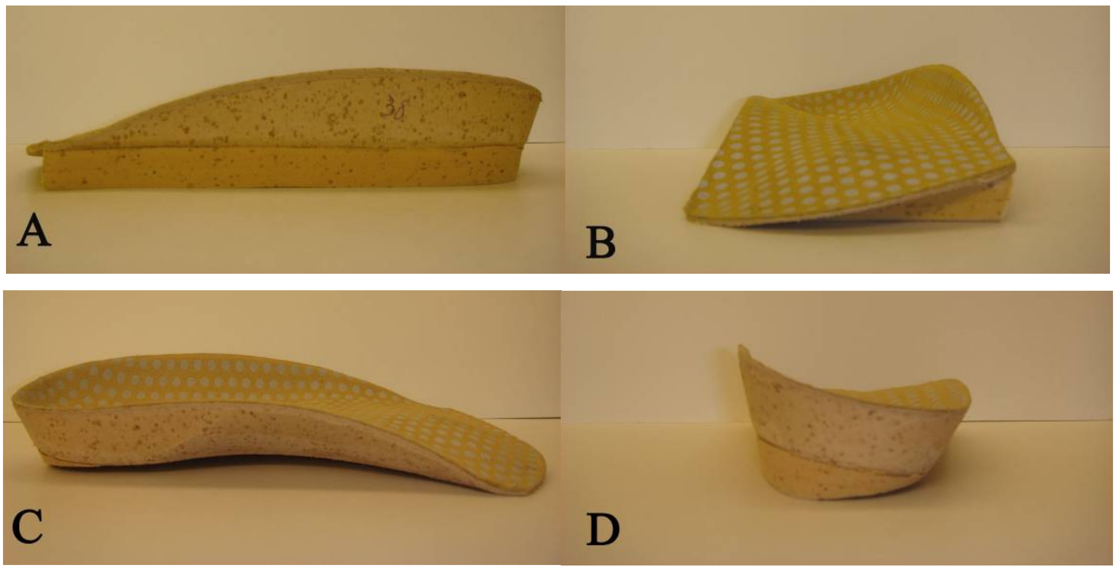

Figure 2. Construction of the lateral wedged insole with an elevation of 12 mm. A. Lateral view. B. Anterior view. C. Medial view. D. Posterior view.

Table 1. Characteristics of the Participants at the Baseline Assessment

	Mean (SD)	Median	95% CI
Age (years old)	71.0 (5.50)	72	68.01 – 73.99
Height (cm)	153.19 (8.63)	151.5	148.5 – 157.88
Weight (kg)	62.69 (7.56)	67.5	58.42 – 66.96
Body mass index (kg/m^2)	26.87 (3.78)	28.13	24.82 – 28.92
Active Range of Motion (right knee)	112.38 (8.32)	115	107.86 – 116.9
Active Range of Motion (left knee)	114.54 (4.65)	115	112.01 – 117.07
Passive Range of Motion (right knee)	119.85 (8.28)	122	115.35 – 124.35
Passive Range of Motion (left knee)	124.15 (4.63)	125	121.64 – 126.66
Lequesne index	10.08 (1.67)	10	9.18 – 10.98
Visual Analog Scale score (mm)	53.62(10.66)	48	47.83 – 59.41

Note: n=13, Female: Male = 9:4

Table 2. Comparison of Radiographic Angles Among the Baseline, Immediate, and Three-month Assessments (n=13)

	Femorotibial angle			Talocalcaneal angle			Talar Tilt Angle		
	Baseline	Immediate	3 months	Baseline	Immediate	3 months	Baseline	Immediate	3 months
Right knee									
Mean (SD)	175.5(3.02)	175.1 (2.94)	175.1 (2.58)	5.38 (3.22)	5.08 (2.99)	5.69 (2.91)	5.69 (3.19)	5.46 (3.18)	7.23 (4.28)
Median	175	175	174	4	5	5	6	6	5
95% CI	173.9-177.1	173.5-176.7	173.2-177	3.63-7.13	3.45-6.71	4.11-7.27	3.96-7.42	3.73-7.19	4.9-9.56
		P=0.35			P=0.79			P=0.63	
			P=0.54			P=0.72			P=0.42
Left knee									
Mean (SD)	175.2 (2.27)	174.4 (2.52)	174.4 (1.23)	6 (4.29)	5.15 (3)	5.23 (4.18)	6 (2.33)	5.85 (2.92)	7 (3.78)
Median	175	175	174	5	4	6	6	7	8
95% CI	174-176.4	173-175.8	173.7-175.1	3.67-8.33	3.52-6.78	2.96-7.5	4.73-7.27	4.26-7.44	4.95-9.05
		P=0.06			P=0.49			P=0.78	
			P=0.18			P=0.83			P=0.66

Table 3. Comparison of VAS Score and Lequesne Index Between the Baseline and Three-month Assessments (n = 13)

	VAS score		Lequesne index	
	Baseline	3 months	Baseline	3 months
Mean (SD)	53.62 (10.66)	38.77 (10.73)*	10.08 (1.67)	6.92 (1.58)†
Median	48	34	10	7
95% CI	47.83 – 59.41	32.94 – 44.6	9.17 – 10.99	6.06 – 7.78

*, †: Significantly different from the baseline assessment; P <0.0001

As for the second reason, the age and OA knee severity of the participants may have led to an undesirable conclusion. Toda and his colleagues[20] suggested that the insole with subtalar strapping was more effective for younger patients and those with a higher proportion of lean body mass per body weight in the lower extremities and less effective for older patients with sarcopenia. The mean age of the participants in our study was 71 years old (with a standard deviation of 5.54). Hence, participants in our study were clearly older than those in the other studies. Furthermore, the radiographic findings, K-L grade for the stage, and the degree of bone destruction in our study were more severe compared with those of other studies. Specifically, when compared with the study of Toda,[20] the average age was 64.4 ± 7.9 year-old and the distribution of Kellgren–Lawrence grade of 46 cases was Grade 2 – 28, Grade 3 – 13, and Grade 4 – 5.

For the third reason, we used the femorotibial, the talocalcaneal, and the talus tilt angles as our evaluation tools as previous studies have likewise done. These three angles were obtained from the static standing radiographs, and these changes of knee OA played minor roles in the detection of radiographical progression during the three-month follow up. The therapeutic effect should be further evaluated during the static and dynamic phases using a motion analysis system, as well as force plates to determine the kinematic and kinetic effects of the treatment in a longer-term clinical follow-up.

The current study was limited in that only 13 participants enrolled. This small number may not have been sufficient in allowing a statistical analysis to evaluate radiographic changes in this study. Further studies should include a larger number of patients to better evaluate the correlation between symptomatic release and radiographic change. Another limitation was the possibility of a placebo effect. To evaluate such an effect, it would be necessary to provide patients with an insole without a lateral wedge. Thus, a placebo group for OA knee patients is needed for comparison. The final limitation of this study was that the selection of outpatients resulted in a bias toward the inclusion of patients who joined the clinical trial because they were reluctant to receive surgical intervention and, therefore, were more likely to have severe OA. Future studies should include a larger number of patients with knee OA of all grades in order to evaluate the effect of the inserted lateral wedged insole.

Other directions for further studies include a more detailed analysis of the therapeutic effect during the static and dynamic phases using a motion analysis system, as well as force plates to determine the kinematic and kinetic effects of the treatment. Moreover, methods for using the lateral wedged insole, the height of the lateral wedge, a more effective material, and optimal duration of the use of the insole should also be studied in the future.

CONCLUSIONS

Inserted lateral wedged insoles were well tolerated by patients with medial knee OA. Despite the lack of significant difference in radiographic change between the baseline and the three-month assessments, the improved VAS score and remission score of the Lequesne index might be considered as indirect support for the efficacy of the lateral wedged insoles. Thus, the use of an orthotic device is one possible choice for patients with knee OA who are reluctant to undergo surgical treatment. This device may also improve their quality of life while simultaneously reducing costs and complications.

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外側楔型鞋墊對內側膝退化性關節炎患者之療效

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背景：內側膝退化性關節炎是造成老年人慢性失能的主要原因之一。本研究主要在評估將內襯型外側楔型鞋墊當作內側膝退化性關節炎保守治療的效果。

方法：針對十三名內側膝退化性關節炎患者(九名女性，四名男性，平均年齡 71.0 ± 5.5 歲)給予外側高 12 毫米的楔型鞋墊治療三個月。比較患者穿之前和三個月之後的自主疼痛指數和 Lequesne index。另外，比較穿鞋墊前，後以及三個月後站立 X 光檢查的股骨脛骨夾角，距骨傾斜角和距骨跟骨夾角。

結果：患者在穿外側楔型鞋墊三個月後，在自主疼痛指數和 Lequesne index 有明顯改善(P<0.0001)。至於穿鞋墊前，後以及三個月後站立 X 光檢查的所有角度並沒有明顯變化。

結論：內襯型外側楔型鞋墊對於內側膝退化性關節炎患者確實會減輕症狀，但在靜態 X 光檢查上並沒有明顯變化。更進一步的步態分析來了解運動學和動力學參數的變化是必要的。更長時間的追蹤以瞭解外側楔型鞋墊的長程效果和避免負面作用是相當重要的。(台灣復健醫誌 2007；35(4)：197 - 205)

關鍵字：鞋墊(insole)，外側楔型(lateral wedged)，退化性膝關節炎(knee osteoarthritis)，輔具(orthotic device)，放射學(radiography)

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