

Prospective study on the effects of orthotic treatment for medial knee osteoarthritis in Chinese patients: clinical outcome and gait analysis

Henry CH Fu, Chester WH Lie *, TP Ng, KW Chen, CY Tse, WH Wong

ABSTRACT

Objective: To evaluate the effectiveness of various orthotic treatments for patients with isolated medial compartment osteoarthritis.

Design: Prospective cohort study with sequential interventions.

Setting: University-affiliated hospital, Hong Kong.

Patients: From December 2010 to November 2011, 10 patients with medial knee osteoarthritis were referred by orthopaedic surgeons for orthotic treatment. All patients were sequentially treated with flat insole, lateral-wedged insole, lateral-wedged insole with subtalar strap, lateral-wedged insole with arch support, valgus knee brace, and valgus knee brace with lateral-wedged insole with arch support for 4 weeks with no treatment break. Three-dimensional gait analysis and questionnaires were completed after each orthotic treatment.

Main outcome measures: The Western Ontario and McMaster Universities Arthritis Index (WOMAC), visual analogue scale scores, and peak and mean knee adduction moments.

Results: Compared with pretreatment, the lateral-wedged insole, lateral-wedged insole with arch support, and valgus knee brace groups demonstrated significant reductions in WOMAC pain score (19.1%, $P=0.04$; 18.2%, $P=0.04$; and 20.4%, $P=0.02$, respectively). The lateral-wedged insole with arch support group showed the greatest reduction in visual analogue scale score compared with pretreatment at 24.1% ($P=0.004$). Addition of a subtalar strap to lateral-wedged insoles (lateral-wedged insole with

subtalar strap) did not produce significant benefit when compared with the lateral-wedged insole alone. The valgus knee brace with lateral-wedged insole with arch support group demonstrated an additive effect with a statistically significant reduction in WOMAC total score (-26.7%, $P=0.01$). Compliance with treatment for the isolated insole groups were all over 90%, but compliance for the valgus knee brace-associated groups was only around 50%. Gait analysis indicated statistically significant reductions in peak and mean knee adduction moments in all orthotic groups when compared with a flat insole.

Conclusions: These results support the use of orthotic treatment for early medial compartment knee osteoarthritis.

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¹ HCH Fu, MB, BS, MMedSc

² CWH Lie *, FRCS (Edin), FHKAM (Orthopaedic Surgery)

³ TP Ng, FRCS (Edin), FHKAM (Orthopaedic Surgery)

⁴ KW Chen, BSc

⁴ CY Tse, BSc

⁴ WH Wong, Diploma in Prosthetics and Orthotics

¹ Department of Orthopaedics and Traumatology, Queen Mary Hospital, Pokfulam, Hong Kong

² Department of Orthopaedics and Traumatology, Kwong Wah Hospital, Yaumatei, Hong Kong

³ Private Practice, Hong Kong

⁴ Department of Prosthetics and Orthotics, Queen Mary Hospital, Pokfulam, Hong Kong

* Corresponding author: chesterliewh@gmail.com

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New knowledge added by this study

- Our data support the use of the lateral-wedged insole with arch support and valgus knee brace in the management of medial compartment osteoarthritis of the knee; however, compliance with the valgus knee brace is fair. Gait analysis showed that both supports can reduce the knee adduction moment during walking.

Implications for clinical practice or policy

- Lateral-wedged insoles with arch support and valgus knee brace can be considered for patients with medial compartment osteoarthritis of the knee.

Introduction

Osteoarthritis of the knee is the commonest type of arthritis affecting the geriatric population.

Conservative treatment with physiotherapy and analgesics provides temporary relief of symptoms, yet surgical intervention such as high tibial

osteotomy, unicompartmental knee replacement, or total knee replacement is a major undertaking and not without risk.^{1,2} The medial compartment is more commonly affected than the lateral compartment in osteoarthritis (67% and 17%, respectively).³ Varus alignment of the lower limbs increases the risk of incident knee osteoarthritis and also increases the risk of disease progression in patients with osteoarthritis.⁴ Apart from static lower limb alignment, dynamic varus thrust during the gait cycle is also independently associated with osteoarthritis progression in the knee.⁵ Knee adduction moment (KAM) is an indirect means to assess varus thrust during the gait cycle. Previous studies have proven the validity of KAM for prediction of clinical and radiological osteoarthritis progression.⁶

Orthotic treatment can alter loading to the knee in the hope of reducing symptoms and disease progression. Biomechanical studies have demonstrated a small effect size in reduction of KAM with a valgus knee brace⁷⁻¹⁰ and lateral-wedged insoles.¹¹⁻¹⁴ This study is the first to sequentially evaluate the clinical outcomes and gait analyses of different orthotic treatments in Chinese patients with medial compartment osteoarthritis.

Methods

Patients

From December 2010 to November 2011, 18 patients with isolated medial osteoarthritis of the knee were referred by orthopaedic surgeons to the Department of Prosthetics and Orthotics at Queen Mary Hospital for orthotic treatment.

The inclusion criteria were age older than 50 years and a diagnosis of osteoarthritis according to the American College of Rheumatology criteria.¹⁵ The predominant symptom needed to be medial knee pain. Radiographical features needed to include varus knee alignment and osteoarthritis of Kellgren-Lawrence grade 2 or above over the medial compartment.¹⁶

Our study population comprised patients with isolated medial compartment osteoarthritis, while patients with predominant lateral compartment or patellofemoral joint symptoms or those with radiographical features of osteoarthritis of Kellgren-Lawrence grade 2 or above over the lateral compartment or patellofemoral joint were excluded.

Patients with previous knee surgery, fixed flexion deformity of >10°, hip or ankle pathology, required a walking aid, or had morbid obesity (body mass index, >40 kg/m²), a dermatological condition, or peripheral vascular disease were also excluded.

This was a non-randomised prospective cohort study with a cross-over design. All 10 patients were sequentially treated with a flat insole (FI), lateral-wedged insole (LW), lateral-wedged insole with

矯形治療對於內側膝退化性關節炎華籍患者的效果：臨床結果和步態分析的前瞻性研究

傅俊謙、李威鴻、吳子培、陳金偉、謝靜怡、黃偉興

目的：評估各種矯形治療對於內側膝單室退化性關節炎患者的效果。

設計：連續性干預的前瞻性隊列研究。

安排：香港一所大學附屬醫院。

患者：從2010年12月到2011年11月，由骨科醫生轉介須進行矯正治療的內側膝退化性關節炎共有10例。所有患者均連續四週逐一接受以下治療：平鞋墊、外側楔型鞋墊、以綁帶將外側楔型鞋墊綁在腳底下、外側楔型鞋墊搭配足弓墊、護膝，以及外側楔型鞋墊搭配足弓墊並加上護膝。每次治療後均進行三維步態分析，並讓患者填寫問卷。

主要結果測量：西安大略和麥克馬斯特大學關節炎指數 (WOMAC)、視覺模擬量表評分，以及峰值和平均膝蓋內收力矩。

結果：與治療前相比，外側楔型鞋墊、外側楔型鞋墊搭配足弓墊和護膝治療的WOMAC疼痛子量指數顯著減少（其比率和P值依次為：19.1%，P=0.04；18.2%，P=0.04；20.4%，P=0.02）。與治療前相比，外側楔型鞋墊搭配足弓墊治療的視覺模擬量表得分改善幅度最大（24.1%；P=0.004）。至於以綁帶將外側楔型鞋墊綁在腳底下的治療，與單獨使用外側楔型鞋墊相比，並沒有明顯改善。外側楔型鞋墊搭配足弓墊並加上護膝的治療得到累加效應，其WOMAC總指數顯著下降（-26.7%，P=0.01）。所有使用外側楔型鞋墊的病人依從性均超過九成，可惜搭配護膝治療的依從性只有五成左右。步態分析顯示與平鞋墊比較，所有治療的峰值和平均膝蓋內收力矩均顯著下降。

結論：以上結果支持應在早期使用矯形治療醫治內側膝退化性關節炎。

subtalar strap (LW+SS), lateral-wedged insole with arch support (LWAS), valgus knee brace (VKB), and valgus knee brace with lateral-wedged insole with arch support (VKB+LWAS). The FI group acted as a control during gait analysis to mimic normal walking. The designs of the orthotics are shown in Figure 1. The insoles were custom-made in the Department of Prosthetics and Orthotics at Queen Mary Hospital, while the Unloader valgus knee braces (Össur hf, Reykjavik, Iceland) were ordered for each patient after measurement. Each of the orthotic treatments was prescribed for 4 weeks and each patient underwent 24 weeks of treatment to use all six orthotics.

For subjective clinical outcomes, pain scores using the visual analogue scale (VAS) and version 3.1 of the Chinese-validated Western Ontario and McMaster Universities Arthritis Index (WOMAC) were measured. The VAS, with a scale from 0 to 10, was used purely for pain severity. The WOMAC score was ascertained by a self-administered questionnaire consisting of 24 items and subdivided into three categories: pain (5 items), stiffness (2 items), and difficulty performing daily activities (17



FIG 1. Various orthotic treatments: (a) valgus knee brace, (b and c) lateral-wedged insole with subtalar strap, (d) lateral-wedged insole, and (e and f) lateral-wedge with arch support

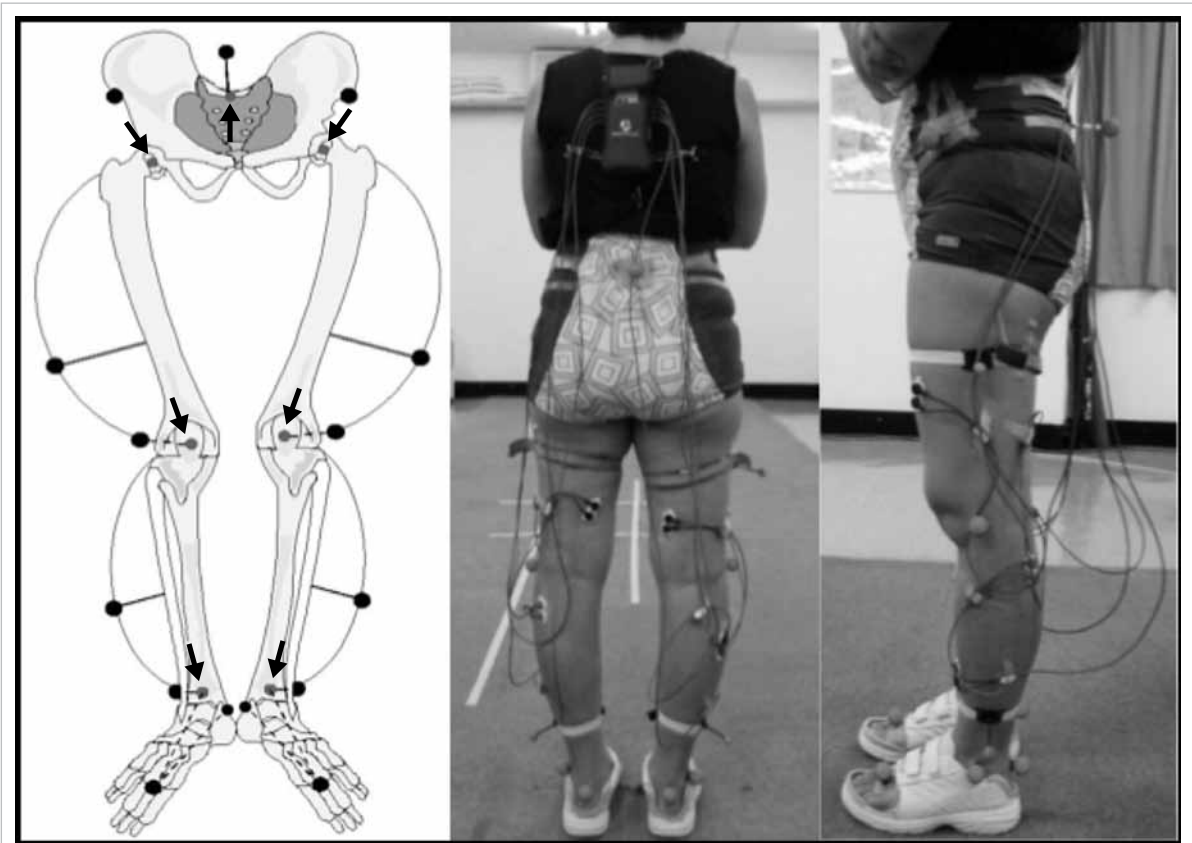


FIG 2. Placement of retro-reflective markers (arrows) for gait analysis

items). Analgesic use (number of times required per week) was also compared. Pretreatment and interval assessments were completed after each orthotic treatment. Paired *t* test was used for analysis.

Gait analysis

Three-dimensional gait analyses were performed for each patient both before and during use of each orthotic treatment at the gait laboratory at the Duchess of Kent Children’s Hospital, Hong Kong, which is an affiliated hospital within the same cluster as Queen Mary Hospital.

Fifteen retro-reflective markers were placed according to the Plug in Gait model (Vicon Industries, Inc, Edgewood [NY], US) as shown in Figure 2. The markers were placed at the bilateral anterior superior iliac spines, midway between the posterior superior iliac spine, lateral epicondyle of the knee,

lateral lower third of the thigh, lateral malleolus, lower third of the shin, second metatarsal head, and calcaneus at the level of the second metatarsal head. Three-dimensional positions of the markers and kinematic data were collected by six cameras using the 370 motion analysis system (Vicon Industries, Inc) at a sampling frequency of 60 Hz. Kinetic data were collected using the 370 motion analysis system synchronised with a multicomponent force platform (Kistler, Winterthur, Switzerland) at 60 Hz.

Peak and mean KAMs during the stance phase of the gait cycle were measured. Mechanical alignment throughout the gait cycle was derived from the hip centre, knee centre, and ankle centre from the retro-reflective markers. After data collection from the gait analysis laboratory, data were analysed jointly by orthopaedic surgeons and prosthetic and orthotic specialists who had a

TABLE I. Comparison of subjective pretreatment and post-treatment scores for various orthotics

	WOMAC			Total	VAS (1-10)
	Part A (Pain)	Part B (Stiffness)	Part C (Activities of daily living)		
Pretreatment					
Mean	54.4	54.4	48.8	48.1	5.5
Flat insole					
Mean	48.6	47.3	46.4	45.0	5.5
% Reduction	-10.6	-12.2	-4.8	-6.5	-0.86
P value	0.11	0.17	0.41	0.25	0.82
Lateral-wedged insole					
Mean	44.0	43.1	47.8	44.4	5
% Reduction	-19.1	-20.0	-2.0	-7.8	-10.3
P value	0.04	0.10	0.72	0.23	0.14
Lateral-wedged insole with subtalar strap					
Mean	47.3	43.8	47.2	45.1	4.9
% Reduction	-13.0	-18.7	-3.3	-6.3	-11.2
P value	0.12	0.09	0.69	0.43	0.15
Lateral-wedged insole with arch support					
Mean	44.5	45.5	44.6	42.8	4.2
% Reduction	-18.2	-15.5	-8.5	-11.1	-24.1
P value	0.04	0.11	0.25	0.14	0.004
Valgus knee brace					
Mean	43.3	47.9	46.1	43.6	4.7
% Reduction	-20.4	-11.1	-5.6	-9.3	-15.5
P value	0.02	0.15	0.56	0.28	0.04
Valgus knee brace with lateral-wedged insole with arch support					
Mean	38.4	43.7	35.9	35.3	4.3
% Reduction	-29.4	-18.8	-26.4	-26.7	-22.4
P value	0.001	0.02	0.002	0.001	0.004

Abbreviations: VAS = visual analogue scale score; WOMAC = Western Ontario and McMaster Universities Arthritis Index

TABLE 2. Mean knee adduction moment for various orthotic treatments

	Mean KAM (Nm/kg)	Standard deviation	% Reduction compared with FI	P value
FI	0.201	0.071	-	-
LW	0.164	0.069	-18.1	<0.001
LW+SS	0.165	0.064	-17.6	0.01
LWAS	0.181	0.071	-9.7	0.02
VKB	0.170	0.072	-15.5	0.001
VKB+LWAS	0.168	0.071	-16.3	0.003

Abbreviations: FI = flat insole; KAM = knee adduction moment; LW = lateral-wedged insole; LWAS = lateral-wedged insole with arch support; SS = subtalar strap; VKB = valgus knee brace

TABLE 3. Peak knee adduction moment for various orthotic treatments

	Peak KAM (Nm/kg)	Standard deviation	% Reduction compared with FI	P value
FI	0.568	0.203	-	-
LW	0.494	0.168	-13.1	0.001
LW+SS	0.461	0.170	-18.8	0.002
LWAS	0.491	0.171	-13.7	0.003
VKB	0.461	0.161	-18.9	<0.001
VKB+LWAS	0.449	0.167	-21.0	<0.001

Abbreviations: FI = flat insole; KAM = knee adduction moment; LW = lateral-wedged insole; LWAS = lateral-wedged insole with arch support; SS = subtalar strap; VKB = valgus knee brace

background in biomedical engineering. Gait analysis comparison was made with the FI group and baseline control data. An assumption was made that the flat insole would not alter the knee kinematics. The control data from the gait laboratory consisted of 47 aged-matched healthy participants with normal gait pattern.

Paired *t* tests were used for comparison of different gait parameters between the orthotic type and baseline measurement.

Results

Eighteen patients (36 knees) were initially recruited into our study. Nineteen knees of 10 patients completed the study, and the remaining eight patients withdrew for personal reasons. Of the 10 patients, nine had bilateral disease and one had unilateral disease. Ten knees were right knees and nine were left knees. There were six women and four men. The mean age of the patients was 56 years (range, 51-65 years). The pretreatment motion arc ranged from 65° to 140° (mean, 122°).

The changes in mean WOMAC and VAS scores for various orthotic treatments and their comparison with pretreatment scores are shown in Table 1. The results of mean and peak KAMs throughout the gait cycle with different orthotics are shown in Figure 3a. The mean and peak KAMs for each orthotic are shown in Tables 2 and 3, respectively. Figure 3b shows

the knee mechanical alignment derived from the hip centre, knee centre, and ankle centre. The initial 65% of the gait cycle represents the stance phase and the later 35% is the swing phase. Compliance with the orthotic treatments is shown in Figure 4.

The LW group demonstrated a significant reduction of 19.1% in the WOMAC pain score ($P=0.04$). Reductions in total and other WOMAC subscale scores, VAS score, and analgesic requirement were observed, but none were statistically significant. Mean and peak KAMs were reduced by 18.1% and 13.1% ($P<0.05$), respectively, when compared with the FI group. The compliance rate was 94.7% of total walking time.

With the addition of subtalar strapping in the hope of increasing the effectiveness of the lateral wedge, the LW+SS group demonstrated a greater reduction of peak KAM (18.8%), but a smaller degree of reduction in mean KAM (17.6%) [$P<0.05$]. The net effect of LW+SS did not confer any statistically significant reduction in VAS score, WOMAC score, or analgesic requirement when compared with the pretreatment scores. The compliance rate for the LW+SS group was 94.7% of total walking time.

The LWAS group demonstrated statistically significant reduction in VAS score of 24.1% ($P=0.004$) and WOMAC pain score of 18.2% ($P=0.04$). Mean and peak KAMs were also significantly reduced by 9.7% and 13.7%, respectively ($P<0.05$). The degree of reduction in VAS score was greatest in

the LWAS group when compared with the LW and LW+SS groups. Score of VAS may be a more reliable predictor of actual symptom improvement than the WOMAC pain score. The compliance rate was also greatest for the LWAS group at 97.4% of total walking time. No significant difference in analgesic requirement was observed.

With respect to mean mechanical alignment, as shown in Figure 3b, all the insole groups (LW, LW+SS, and LWAS) showed lower varus angle throughout the stance phase. The stance phase is the symptomatic phase when the knee is under loading.

The VKB group showed a statistically significant reduction in VAS score and WOMAC pain score of 15.5% ($P=0.04$) and 20.4% ($P=0.02$), respectively. The WOMAC total score and other subscale scores showed some reductions, but these were not statistically significant. The analgesic requirement was also significantly reduced from 1.5 days/week pretreatment to 0.5 days/week post-treatment ($P=0.04$). Mean and peak KAMs were reduced by 15.5% and 18.9%, respectively ($P<0.05$). Mechanical alignment, as seen in Figure 3b, showed reduced varus angulation during the early stance phase. The interval between 15% and 20% of the gait cycle, representing the heel strike to mid-stance phase, was shown to have reduced the varus angle when compared with baseline. The varus angle remained constant throughout the stance phase, which was related to restricted motion of the knee inside the brace. Compliance was significantly lower than that for any of the insole groups at 54.5% of the total walking time. The low compliance rate was likely due to the bulky size of the valgus knee brace causing skin discomfort, especially in the hot and humid climate in this region.

The LWAS seemed to be the best insole treatment for pain relief and improvement in VAS score, so we further evaluated the combination effects of the VKB and LWAS treatments. Additive effects were observed with combined treatment. The VKB+LWAS group showed significant reductions in VAS score, as well as WOMAC total and all subscale scores. Score of VAS reduced by 22.4% ($P=0.004$), WOMAC pain score reduced by 29.4% ($P=0.001$), WOMAC stiffness score reduced by 18.8% ($P=0.02$), WOMAC activities of daily living score reduced by 26.4% ($P=0.002$), and WOMAC total score reduced by 26.7% ($P=0.001$). The extent of reduction in the WOMAC total and subscale scores for this group was the greatest of the treatment groups. The analgesic requirement was also significantly reduced from 1.5 days/week pretreatment to 0.6 days/week post-treatment ($P=0.04$). Peak KAM showed the greatest reduction of all the orthotic groups of 21.0%, while mean KAM showed moderate reduction of 16.3% ($P<0.05$). With regard to the mechanical alignment, reduction in varus angle was observed in the early

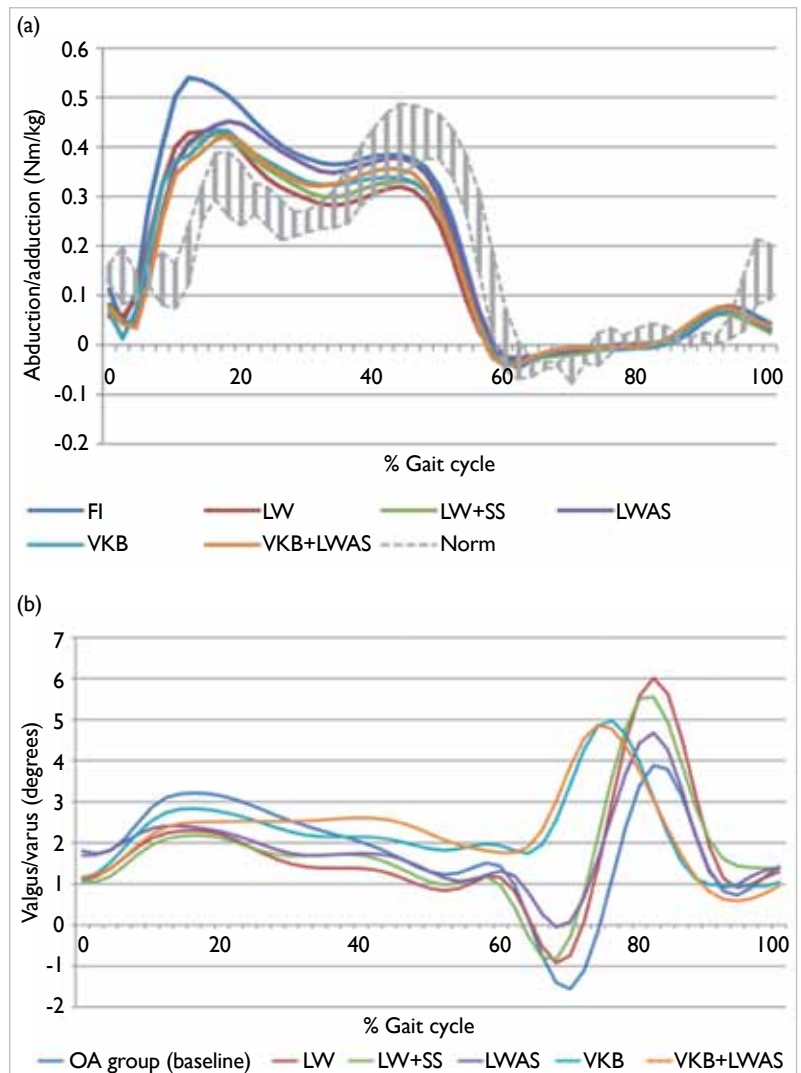
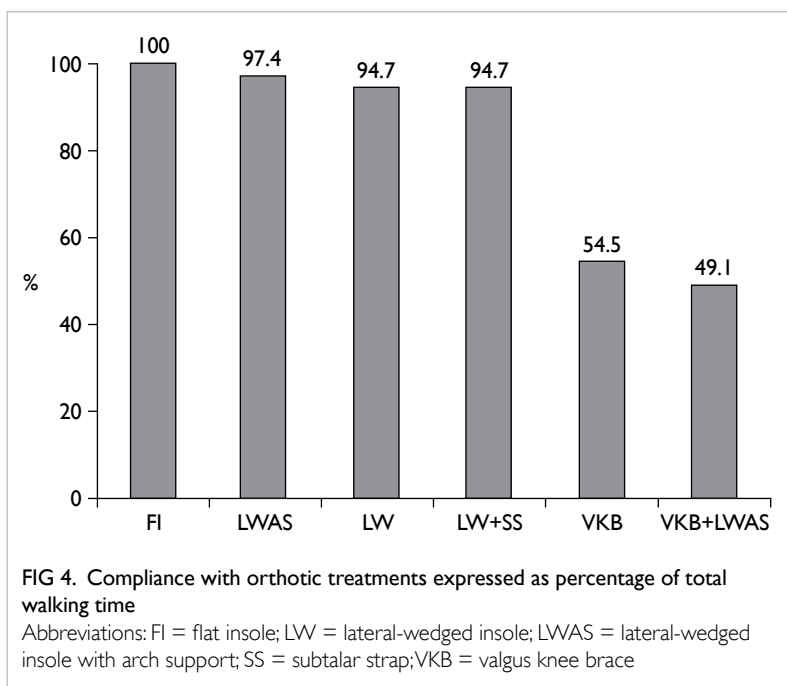


FIG 3. (a) Comparison of knee adduction moments with different orthotic treatments throughout the gait cycle. (b) Comparison of mean mechanical alignment with different orthotic treatments
Abbreviations: FI = flat insole; LW = lateral-wedged insole; LW+SS = lateral-wedged insole with arch support; Norm = normal; OA = osteoarthritis; SS = subtalar strap; VKB = valgus knee brace

stance phase, as in the isolated VKB group. The compliance, as expected, was lowest among all the treatment arms with only 49.1% of total walking time.

Discussion

The current literature recommendations for orthotic treatment for medial compartment knee osteoarthritis are still varied. In a guideline by the Osteoarthritis Research Society International (OARSI), insoles were concluded to be of benefit to reduce pain and improve ambulation in knee osteoarthritis.¹⁷ However, in another guideline by the American Academy of Orthopaedic Surgeons



(AAOS), it was concluded that lateral-wedged insoles could not be suggested for patients with symptomatic osteoarthritis.¹⁸ Lateral-wedged insoles have been shown to correct the femorotibial angle¹⁹ and reduce the peak external KAM.^{12,20} Toda et al²¹ were able to demonstrate a dose-response correction of the femorotibial angle using insoles with different elevations. The effect on subjective scores showed significant improvements in some,²² but not all studies.^{23,24} Two randomised controlled trials by Maillfert et al²³ and Baker et al²⁴ did not show statistically significant changes in WOMAC scores with lateral-wedged insoles, although there was a significant reduction in non-steroidal anti-inflammatory drug intake in the insole group.

Our results showed reduction in WOMAC pain score with LW and LWAS, but more importantly, a greater percentage reduction in VAS score with LWAS. Addition of subtalar strapping to lateral-wedged insoles was shown in other studies to improve VAS scores, and decrease the femorotibial angle²⁵ and peak KAM²⁶ when compared with a lateral-wedged insole alone. The potential drawbacks of subtalar strapping include increased sole pain.²⁷ The results from our study did not demonstrate the additional benefit with subtalar strapping in terms of WOMAC score or mean KAM. With a significantly greater reduction in VAS with LWAS than LW (24.1% vs 10.3%) and a high compliance rate, we believe LWAS is the insole of choice and can be offered to patients with early isolated medial compartment

knee osteoarthritis.

Knee bracing acts by inducing a valgus force by the three-point bending principle. The OARSI guideline suggests that knee bracing could reduce pain, improve stability, and reduce the risk of fall in patients with mild-to-moderate osteoarthritis or valgus instability.¹⁷ However, the guideline from the AAOS could not conclude for or against the use of valgus-directed bracing.¹⁸ Advantages of knee bracing include avoidance of surgery and the potential surgical complications, while the disadvantages include compliance and the cost of manufacturing the brace.²⁸ A randomised controlled trial by Brouwer et al²⁹ compared three treatment groups of valgus knee brace plus medical treatment, insole plus medical treatment, and medical treatment alone. The brace plus medical treatment was shown to have borderline benefit compared to medical treatment alone in terms of pain score and function.²⁹ These findings concur with our study result of improved WOMAC pain subscale score and reduced analgesic requirement with valgus knee brace when compared to pretreatment scores. From the kinetics perspective, Pollo et al⁷ were able to demonstrate reduction in net external KAM by 13%. Our gait analysis model was able to reproduce reduction in mean KAM by 18.9%. Despite the potential benefits from valgus knee brace, compliance remains a major drawback. With a compliance rate of 54.5%, many of our patients claimed that they did not wear the braces outdoors due to skin discomfort in the hot and humid climate. Our evidence would suggest valgus knee brace is suitable for selected patients with mild knee osteoarthritis, with consideration of the problem with fitting and compliance.

Our current study was among the few to evaluate the effects of combination orthotic treatment with valgus knee brace and lateral-wedged insole with arch support. The VKB+LWAS group was the only one to demonstrate significant reductions in WOMAC total and all subscale scores, analgesic use, and KAM when compared with pretreatment. These results further reiterate the dose-response relationship in reducing KAM to achieve improvement in objective knee scores. Despite these findings, the poor compliance rate would render this orthotic treatment less advisable.

Limitations

Limitations of our study included a small sample size, selection bias, self-selection bias, and a short follow-up period. Similar studies of less than 20 patients are seen in many studies of gait analysis.³⁰⁻³² A larger sample size would provide a higher power to determine the statistical significance in more of the evaluated parameters. Compliance with orthotic treatment, in particular with the valgus knee brace, was another concern. Confounding factors in our

study included the frequency of weight-bearing activities, which could be difficult to quantify.

This was a cross-over study, with all patients having to be treated sequentially with all six orthotic combinations. The advantages are an economy of sample size without the need to account for heterogeneity of the patient groups. The disadvantages of the design include lack of a treatment break and lack of randomisation in the treatment sequence. Scores of VAS reported by elderly people may also be inaccurate.

Conclusions

Knee osteoarthritis continues to pose a significant burden to our community with its ageing population and increased incidence of obesity. While operative treatments are not without risk, orthotic treatment also has its advantages and disadvantages. Our current study was able to demonstrate from subjective scores and gait analysis that orthotic treatment can alter knee loading and alleviate symptoms. The lateral-wedged insole with arch support is optimal, while valgus knee brace is equally effective, with fair compliance. Further studies with a larger sample size are required to evaluate the effectiveness in the long term.

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