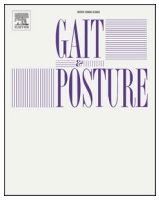
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# Biomechanical effects of a semi-rigid knee orthotic during walking in individuals with medial knee osteoarthritis

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ABSTRACT

*Background:* Medial knee osteoarthritis is associated with increased medial compartment loading during gait. Valgus unloader knee orthotics are commonly used to reduce medial knee loading, but the biomechanical responses associated with semi-rigid designs remain unclear.
*Research question:* After six weeks of use, what effect does the orthotic condition have on first-peak knee adduction moment (KAM), second-peak KAM, and knee adduction angular impulse (KAAI) during constant-speed and self-selected-speed walking compared with baseline in individuals with medial knee osteoarthritis?
*Methods:* Twenty-four participants with Kellgren-Lawrence grade 2–4 completed a within-participant pretest–posttest study. Gait was assessed without the orthotic at baseline and while wearing it after six weeks of use (mean 5.13 h/day), at a constant speed of 1.39 m/s and self-selected speed. In OpenSim, first-peak KAM, second-peak KAM, and KAAI were calculated. GRF variables were secondary, exploratory outcomes. Conditions were compared using paired t-tests or Wilcoxon signed-rank tests. Holm-Bonferroni adjustment was applied to the three KAM-related outcomes within each walking condition.
*Results:* During constant-speed walking, first-peak KAM, second-peak KAM, and KAAI were lower with the orthotic by 6.9% , ($r = 0.44$), 6.8% ($r = 0.47$), and 15.8% ($r = 0.51$), respectively (Holm-adjusted $p = 0.045$ for each). Vertical GRF variables did not differ, whereas the braking-peak magnitude and braking and propulsive impulses increased. During self-selected-speed, participants walked 15.5% faster in the orthotic condition ($p < 0.001$). First- and second-peak KAM did not differ significantly from baseline, whereas KAAI was lower ($-0.030$ N·m·kg$^{-1}$·s, 95% CI $-0.050$ to $-0.010$; Holm-adjusted $p = 0.014$). The first vertical, braking, and propulsive GRF peaks increased, while vertical impulse decreased.
*Significance:* Semi-rigid orthotic use was associated with lower KAM-related loading during constant-speed walking and faster self-selected walking without higher peak KAM. The semi-rigid orthotic may be considered a possible adjunct to individualized, multicomponent care for individuals with medial knee osteoarthritis.

## 1. Introduction

Knee osteoarthritis is a major public health concern because of its high prevalence, substantial societal costs, and the pain and functional limitations experienced by affected individuals [1–3]. Its burden is projected to increase substantially over the coming decades [2]. Medial knee osteoarthritis (mKOA) is the most common compartmental presentation, affecting approximately two-thirds of patients with knee osteoarthritis [4].

Frontal-plane gait biomechanics are considered relevant to mKOA progression because altered dynamic knee loading during walking has been associated with structural disease progression [5]. To characterise this loading, the external knee adduction moment (KAM) is commonly examined. During stance, it results from the ground reaction force (GRF) acting with a frontal-plane lever arm relative to the knee joint centre [6]. KAM-related variables, including peak values and the knee adduction angular impulse (KAAI), are widely used surrogate measures of medial knee joint loading [7–9] and typically differ between patients with mKOA and asymptomatic individuals [10,11]. Although these measures do not directly quantify tibiofemoral contact forces, KAM has been associated with internal knee joint loading, supporting its use as a biomechanical surrogate [8,12].

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Knee orthotics are one such intervention and are used in the conservative management of mKOA to modify frontal-plane knee loading [11,13]. Traditional valgus unloader orthotics apply valgus-directed corrective forces and have been shown to reduce KAM-related measures during gait [14–16]. However, their use may be limited by discomfort, inadequate fit, and poor adherence during daily use [15,17]. In contrast, elastic knee sleeves are less structurally rigid and primarily provide compression and joint support [18]. Their use has been associated with reduced pain and improved balance and gait-related outcomes, although the underlying mechanisms remain incompletely understood [18,19].

Semi-rigid knee orthotics combine an elastic sleeve-like component with structured elements, such as a joint splint and adjustable valgus-directed straps, thereby differing from both knee sleeves and traditional unloader orthotics. They are intended to combine flexible joint support with mechanical unloading, but whether this design improves comfort, adherence, or biomechanical unloading during daily activities compared with other orthotic types remains unclear. Previous research has reported reduced pain and improved patient-reported mobility and daily functioning with semi-rigid orthotic use [20]. In our previous study of the same cohort analysed in the present study, six weeks of regular semi-rigid orthotic use was associated with increased six-minute walk distance, fewer limitations in everyday and sport-related activities, improved quality of life, increased vigorous physical activity, and reduced pain during walking [21]. However, whether these functional and symptomatic changes were accompanied by differences in KAM-related measures remains unclear. It is also unknown whether differences in KAM-related measures are accompanied by broader changes in gait biomechanics, as reflected by GRF variables [22].

Walking speed should be considered when evaluating orthotic effects on knee loading because KAM-related measures are speed-dependent [23–25]. Accordingly, changes observed during self-selected walking may partly reflect changes in preferred walking speed, making it difficult to clearly distinguish speed-related from orthotic-related effects on knee loading [26]. Walking at a constant prescribed speed controls for between-assessment differences in walking speed and enables assessment under standardised locomotor conditions, whereas self-selected walking may better reflect the individual's habitual gait strategy and the resulting mechanical loading [27,28]. Thus, both conditions capture distinct aspects of gait-related knee loading and should be considered when investigating orthotic effects on knee loading.

Therefore, the present study investigated whether KAM-related measures were lower while walking with a semi-rigid knee orthotic after six weeks of regular use than during baseline walking without the orthotic. Constant-speed walking was specified as the primary standardised condition, whereas self-selected-speed walking was included as a complementary condition reflecting participants' freely chosen walking pace. The primary outcomes were first- and second-peak KAM and KAAI; GRF variables were secondary exploratory outcomes. We hypothesised that all three KAM-related outcomes would be lower in the orthotic condition than at baseline during constant-speed walking. During self-selected-speed walking, we hypothesised that participants would walk faster in the orthotic condition without corresponding increases in first-peak KAM, second-peak KAM, or KAAI.

## 2. Methods

### 2.1. Participants

This study used a within-participant pretest-posttest design and included 24 participants with mKOA, diagnosed using combined clinical and radiographic criteria. This manuscript reports an additional biomechanical analysis of the cohort previously described by Stetter et al. [21] which focused on pain, physical activity, and functional outcomes. The same assessment time points, baseline and after six weeks of regular orthotic use, were selected for the present biomechanical analysis to facilitate interpretation alongside the previously reported clinical findings.

Participants were recruited as a convenience sample through announcements in a local newspaper and university information events on knee osteoarthritis care. Eligibility required symptomatic tibiofemoral osteoarthritis with predominantly medial compartment involvement, defined as Kellgren-Lawrence (K-L) grade 2–4 with greater medial than lateral joint-space narrowing, and varus alignment. Participants were required to report knee pain during activities of daily living within the previous 3 months and reduced knee function. The Knee Injury and Osteoarthritis Outcome Score (KOOS) was used to further characterise participants' self-reported symptoms and functional status. The contralateral knee had to be clinically asymptomatic and show no more than mild radiographic osteoarthritis (K-L grade $\leq$ 2). Radiographic severity was assessed using the K-L grading system [29] by an orthopaedic surgeon with clinical expertise in knee osteoarthritis. Exclusion criteria were contraindications to radiographic examination, a body mass index $\geq$ 35 kg/m$^2$, and other orthopaedic or musculoskeletal conditions affecting the lower limbs or back that could influence gait, such as rheumatoid arthritis, acute disc herniation, or joint endoprostheses. Participant characteristics are summarised in Table 1.

The study was approved by the Ethics Committee of the Karlsruhe Institute of Technology. All participants received written study information and provided written informed consent before participation.

### 2.2. Knee orthotic and bench testing

After the baseline assessment, participants were individually fitted with a semi-rigid knee orthotic (GenuTrain OA, Bauerfeind AG, Zeulenroda-Triebes, Germany) by an experienced orthopaedic technician. The orthotic included an adjustable strap system and a built-in joint splint intended to generate an external knee abduction moment, thereby counteracting varus alignment and reducing medial compartment loading.

The orthotic-induced knee abduction moment was quantified using a standardised test rig [30] consisting of femoral and tibial phantoms, to which the orthotic was attached according to its intended anatomical placement (Fig. 1A). The femoral phantom was fixed, whereas the tibial phantom was displaced continuously in the frontal plane from 0° to 9° of adduction at 0.3°/s. The test was designed to characterise the frontal-plane mechanical response of the orthotic under standardised quasi-static conditions. The slow displacement rate was selected to minimise acceleration-dependent effects of the test setup and enable reproducible determination of the orthotic moment-angle relationship. Tibial adduction loaded the orthotic and generated an external abduction moment opposing the applied motion.

**Table 1**
Participant and mKOA characteristics [21].

| Variable | Total |
|---|---|
| Number | 24 |
| Sex (female/male) | 10/14 |
| Age (years) | 61.4 ± 7.2 |
| Height (m) | 1.70 ± 0.1 |
| Body mass (kg) | 76.3 ± 14.4 |
| Body mass index (kg·m$^{-2}$) | 26.4 ± 4.0 |
| Side involved (left/right) | 13/11 |
| K-L Score (Grade 2/Grade 3/Grade 4) | 6/12/6 |
| Varus alignment (°) | 5.57 ± 2.1 |
| KOOS Pain | 64.4 ± 16.7 |
| KOOS Symptoms | 69.3 ± 17.3 |
| KOOS Activities of daily living | 74.7 ± 15.0 |
| KOOS Sports and leisure activities | 47.3 ± 27.4 |
| KOOS Quality of Life | 41.5 ± 15.7 |

Data are presented as mean ± standard deviation unless otherwise indicated. K-L: Kellgren-Lawrence. KOOS: knee injury and osteoarthritis outcome score (0–100, 0 = worst, 100 = best).

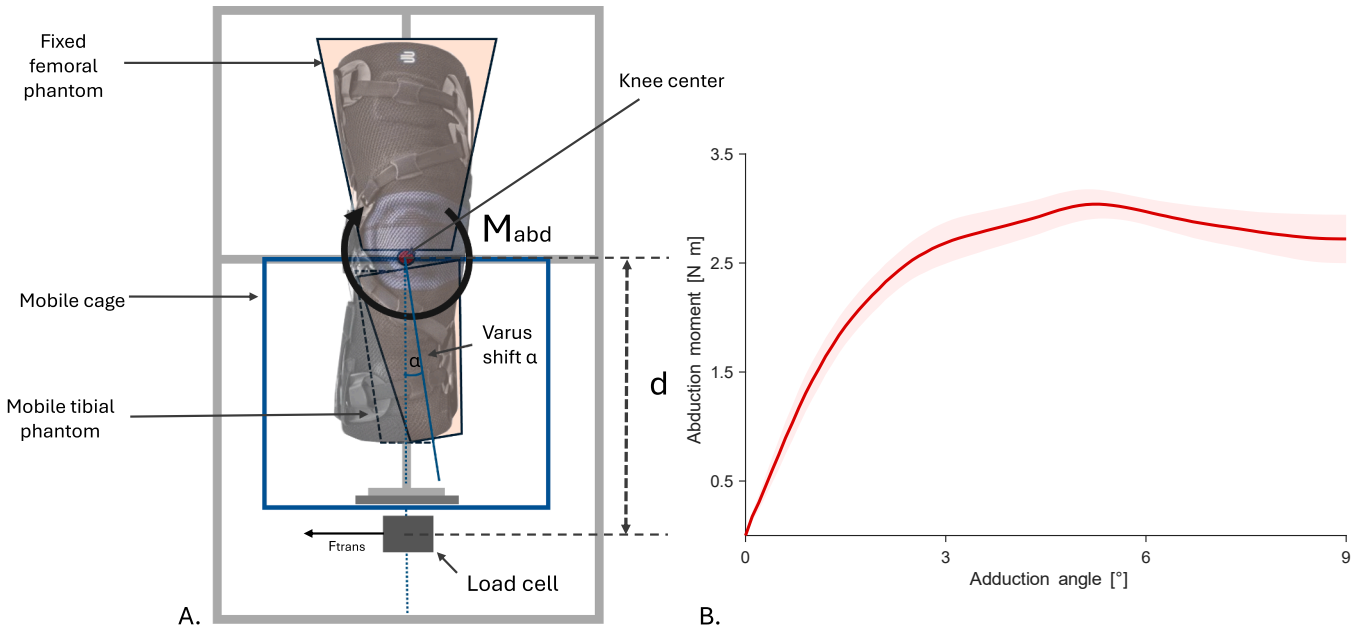



**Fig. 1. A.** Schematic illustration of the test setup for quantifying the orthotic-induced knee abduction moment. The femoral phantom was fixed, whereas the tibial phantom was displaced in the frontal plane to load the orthotic. A six-axis force-moment sensor mounted distal to the knee joint measured the transverse force ($F_{trans}$) acting on the tibial segment. The orthotic-induced knee abduction moment ($M_{Abd}$) was calculated as the product of $F_{trans}$ and the corresponding moment arm (d) relative to the knee centre. **B.** Mean orthotic-induced knee abduction moment as a function of adduction angle. The black line shows the mean curve, and the shaded area represents ±1 standard deviation across repetitions.

A manufacturer-calibrated six-axis force-moment sensor (K6D68 1 kN/100 Nm, ME-Meßsysteme GmbH, Germany) was mounted distal to the knee joint and measured the transverse force acting on the tibial phantom in the frontal plane. The manufacturer-provided calibration matrix was used to convert the sensor output to forces and moments. The signal was sampled at 10 Hz and processed using a zero-phase fourth-order Butterworth low-pass filter with a cut-off frequency of 0.2 Hz. The orthotic-induced abduction moment ($M_{Abd}$) was calculated as $M_{Abd} = F_{trans} \cdot d$, where $F_{trans}$ was the measured transverse force and d was the corresponding moment arm relative to the knee centre.

To account for tibial phantom weight and system-related baseline loading, a reference trial without the orthotic was performed and subtracted from the measured signal. Seven repetitions were conducted, with the orthotic reapplied before each repetition, to account for variability associated with repeated orthotic positioning and to derive an averaged moment-angle relationship. Mean and standard deviation of $M_{Abd}$ were calculated across repetitions at each adduction angle. Between-repetition variability was additionally quantified as the coefficient of variation (CV; standard deviation/mean × 100) of $M_{Abd}$ at each adduction angle. Given the instability of CV when the mean approaches zero, the median, minimum, and maximum of the angle-specific CVs were calculated over the participant-relevant alignment range of 1.37–9.0°.

To determine participant-specific $M_{Abd}$, the mean orthotic-induced abduction moment-angle curve from seven bench-test repetitions was linearly interpolated and evaluated at each participant's individual frontal-plane varus alignment (Fig. 1B), as determined in Section 2.4. The resulting moment was incorporated into the musculoskeletal modelling workflow as described in Section 2.4.

### 2.3. Biomechanical data acquisition

Biomechanical data were collected under two assessment conditions: at baseline without the orthotic and after six weeks of regular use while participants wore the orthotic. The six-week period was selected to allow familiarisation with the orthotic while limiting the potential for adherence to decline over a longer intervention period [31–33]. Participants were instructed to wear the orthotic for at least 5 h/day during daily activities, including exercise and sports, consistent with previously reported daily orthotic-wearing regimens [33,34]. As previously reported for this cohort, mean daily wear time was 5.13 ± 2.95 h/day [21]. Wear time was objectively recorded using a temperature sensor integrated into the orthotic. They were also asked to maintain their usual treatment behaviour; any additional therapy was to be documented in a daily diary. None were reported during the intervention period and no adverse events were observed or reported during orthotic use or biomechanical testing.

At both assessments, three-dimensional gait analysis was performed while participants walked barefoot along a 6 m walkway under two walking-speed conditions: a constant speed of 1.39 m/s and a self-selected speed reflecting each participant's freely chosen walking pace [35]. The constant-speed condition enabled comparison of KAM-related measures while minimising the influence of walking speed differences between assessments [23,25]. The target speed of 1.39 m/s was selected a priori based on pilot measurements and was feasible for all participants at both assessments. This was consistent with the relatively preserved walking capacity of the cohort, which covered 534.8 ± 75.7 m during the baseline 6-minute walk test, corresponding to an average walking speed of approximately 1.49 m/s [21]. Before data collection, participants completed three to five practice trials to familiarise themselves with the walkway, the test setup, and both walking-speed conditions.

Marker trajectories were recorded using a motion capture system (16 cameras, 200 Hz; Vicon Motion Systems, Oxford, UK) with 62 reflective markers placed on anatomical landmarks and were post-processed in Vicon Nexus Version 2.12. For orthotic gait trials, knee markers were attached to the orthotic. For each walking condition (1.39 m/s and self-selected), three valid trials, i.e. correct foot placement on the force plate, were recorded. GRFs were collected using two force plates (1000 Hz; AMTI Inc., Watertown, MA, USA). Walking speed was monitored at the walkway centre using a timing light system (TAG Heuer, La Chaux-de-Fonds, Switzerland) with sensors placed 2 m apart. Constant-speed trials were accepted within ±10% of the target speed.

### 2.4. Musculoskeletal modelling

Musculoskeletal modelling was performed using OpenSim 4.4 (Stanford University, Stanford, CA, USA) to determine KAM. Experimental data (GRF and 3D marker trajectories) were processed in MATLAB R2025b. GRFs were applied at the centre of pressure and low-pass filtered using a bidirectionally applied second-order Butterworth filter with a cut-off frequency of 20 Hz [36]. The OpenSim 4.4 Scale, Inverse Kinematics, and Inverse Dynamics tools were executed from custom MATLAB scripts via the OpenSim MATLAB API.

A generic musculoskeletal model [37] with 23 degrees of freedom was used, including 6 degrees of freedom for the pelvis, three for the lumbar joint, three for each hip, two for each knee, and one each for the ankle and subtalar joints. The knee joint included rotations in the sagittal and frontal planes. To account for individual varus alignment, a multi-compartment knee model [38] was implemented [39].

Participant-specific frontal-plane varus alignment of the affected knee was determined during a standardised static standing assessment performed by the same examiner. Anatomical landmarks were identified by palpation and used to define the hip, knee, and ankle joint centres, which were subsequently marked on the participant. A laser was used to project the mechanical axis of the lower limb - the Mikulicz line connecting the hip and ankle joint centres [40]. The perpendicular distance from the Mikulicz line to the knee joint centre and the hip-to-knee and knee-to-ankle joint-centre distances were measured. The hip-knee-ankle angle was calculated geometrically from these distances, with varus alignment defined as its deviation from 180°. This participant-specific alignment was implemented in the generic musculoskeletal model.

The resulting model was scaled to each participant using anthropometric data and marker positions from a static standing trial. Scaling was accepted when the maximum marker error was $< 2$ cm and the root-mean-square error (RMSE) was $< 1$ cm. Inverse-kinematics solutions were accepted when the maximum marker error was $< 4$ cm and the RMSE was $< 2$ cm. Joint kinematics were low-pass filtered within the OpenSim workflow using a cut-off frequency of 6 Hz.

In the orthotic condition, the participant-specific $M_{Abd}$ derived from bench testing was applied to the tibial segment as an external frontal-plane moment during inverse dynamics. The moment was expressed in the local tibial coordinate system and applied about its anterior-posterior axis. Its sign was adjusted according to the affected side so that it consistently represented a knee abduction moment. The participant-specific magnitude of $M_{Abd}$ was held constant throughout the analysed stance phase. This external moment accounted for the mechanical contribution of the orthotic, which is not represented in conventional inverse dynamics unless incorporated as an additional external load [41]. The orthotic mass (0.382–0.484 kg, depending on size) was not incorporated into the musculoskeletal model.

### 2.5. Outcome variables and data reduction

KAM and GRF time series were time-normalised to the stance phase of gait (101 time points). Heel strike and toe-off were determined from the vertical GRF by applying a threshold of 25 N [36]. Only the affected limb was analysed.

KAM values were normalised to body mass and expressed in $N{\cdot}m{\cdot}kg^{-1}$ . For subsequent analyses, the first and second peak KAM were extracted from the stance phase KAM time series. KAAI was calculated as the time integral of the non-normalised KAM over the actual stance duration and subsequently normalised to body mass ($N{\cdot}m{\cdot}kg^{-1}{\cdot}s$).

The first and second peaks of the vertical GRF and the braking and propulsive peaks of the anterior-posterior GRF were extracted. The vertical GRF impulse was calculated over the entire stance phase, whereas braking and propulsive impulses were calculated over the respective negative and positive portions of the anterior-posterior GRF curve. All GRF peaks were normalised to body mass and expressed in $N{\cdot}kg^{-1}$ , and GRF impulses were expressed in $N{\cdot}s{\cdot}kg^{-1}$ .

As an additional exploratory post hoc analysis, the frontal-plane GRF lever arm was determined at the time points of the first and second KAM peaks. The lever arm was defined as the perpendicular distance between the resultant frontal-plane GRF line of action and the knee joint centre [6]. For each inverse-kinematics time frame, the global position of the knee joint centre was obtained from the participant-specific scaled OpenSim model and expressed in the ground coordinate system. Following Lewinson et al. [42], the frontal-plane GRF induced moment about the knee was calculated from the vertical and mediolateral GRF components and the corresponding components of the vector from the knee joint centre to the centre of pressure. The absolute lever arm was then calculated by dividing the magnitude of this frontal-plane moment by the magnitude of the resultant frontal-plane GRF and was expressed in centimetres. Lever-arm values at the first and second KAM peaks were averaged across trials within each walking condition.

### 2.6. Statistical analysis

The sample size was determined for the original study based on effect estimates from a pilot study including nine participants. For the original three-time-point repeated-measures design, the calculation indicated required sample sizes of 23 participants for KAM and 9 participants for KAAI at $\alpha = 0.05$ and 80% power. No separate a priori sample-size calculation was performed for the present two-time-point secondary analysis.

Statistical analyses were performed in MATLAB. All variables were tested for normality using the Shapiro–Wilk test and visual inspection of Q-Q plots. Depending on the data distribution, differences between the baseline and the orthotic condition were assessed using paired *t*-tests or Wilcoxon signed-rank tests. Paired changes are reported as mean differences with 95% confidence intervals for paired *t*-tests and as Hodges-Lehmann estimates with 95% confidence intervals for Wilcoxon signed-rank tests.

Effect sizes were calculated to quantify the magnitude of differences. For normally distributed variables, Cohen's $d_z$ was calculated for paired samples [43] and converted to an r-equivalent for comparability [44]. For non-normally distributed variables, effect size r was calculated from the standardised Wilcoxon test statistic as $r = \frac{Z}{\sqrt{N}}$ [44]. R-equivalents were interpreted as small ($r \geq 0.10$), moderate ($r \geq 0.30$), and large ($r \geq 0.50$) effects [45].

The first and second peak KAM and KAAI were considered the main biomechanical outcome variables, as key surrogate measures of medial knee loading. Consistent with the predefined analytical hierarchy and distinct aims of the walking conditions, the three KAM-related outcomes during constant-speed walking constituted the primary inferential family, whereas the corresponding outcomes during self-selected-speed walking constituted a separate complementary inferential family. The constant-speed condition provided a standardised assessment of orthotic-associated biomechanical differences while minimising the influence of between-assessment differences in walking speed, whereas the self-selected-speed condition captured the overall biomechanical response during freely chosen walking, including changes in preferred walking speed and associated gait biomechanics. To control the family-wise Type I error rate within each family, p-values were adjusted using the sequential Holm–Bonferroni procedure [46]. GRF peak and impulse variables were considered secondary exploratory outcomes, whereas the frontal-plane GRF lever-arm variables were derived in an additional exploratory post hoc analysis. P-values for walking speed, GRF outcomes, and frontal-plane GRF lever-arm outcomes were unadjusted. Statistical significance was set a priori at $p < 0.05$.

## 3. Results

### 3.1. Bench testing

Bench testing yielded a mean participant-specific orthotic-induced abduction moment of 2.80 ± 0.30 Nm at participants' individual frontal-plane alignment. Across the participant-relevant tested alignment range (1.37–9.0°), the median between-repetition CV of $M_{Abd}$ was 6.3% (range 4.0–9.1%).

### 3.2. Constant-speed walking condition

During constant-speed walking at 1.39 m/s, all three KAM-related outcomes were lower in the orthotic condition than at baseline (Table 2, Fig. 2). First peak KAM was reduced by 0.040 N·m·kg$^{-1}$ (95% CI: −0.074 to −0.005), corresponding to a 6.9% reduction (r = 0.44; Holm-adjusted p = 0.045). Second peak KAM was 6.8% lower, with a Hodges-Lehmann estimate of the paired difference of −0.045 N·m·kg$^{-1}$ (95% CI: −0.062 to −0.005; r = 0.47; Holm-adjusted p = 0.045). KAAI was reduced by 0.021 N·m·kg$^{-1}$ ·s (95% CI: −0.038 to −0.005), corresponding to a 15.8% reduction (r = 0.51; Holm-adjusted p = 0.045).

The frontal-plane GRF lever arm did not differ significantly between conditions at either KAM peak (Table 2).

For the GRF outcomes, the braking peak became more negative, and both braking and propulsive impulses increased in magnitude (Table 2, Fig. 3). Effect estimates indicated changes of −0.153 N·kg$^{-1}$ for the braking peak (p = 0.007) and −0.017 and 0.014 N·s·kg$^{-1}$ for the braking and propulsive impulses, respectively (p = 0.042 and p = 0.039). The remaining GRF outcomes showed no statistically significant differences (Table 2).

### 3.3. Self-selected-speed walking condition

During self-selected-speed walking, participants walked 0.205 m/s faster in the orthotic condition than at baseline (95% CI: 0.095–0.315; r = 0.66; p < 0.001; Table 3). The paired differences in first and second peak KAM were 0.008 N·m·kg$^{-1}$ (95% CI: −0.030–0.045) and −0.024 N·m·kg$^{-1}$ (95% CI: −0.054–0.007), respectively, neither of which was statistically significant after Holm adjustment. KAAI decreased by 0.030 N·m·kg$^{-1}$ ·s (95% CI: −0.050 to −0.010; r = 0.58; Holm-adjusted p = 0.014) (Table 3, Fig. 4).

During self-selected-speed walking, neither the first nor the second peak frontal-plane GRF lever arm showed a significant between-condition difference (Table 3).

For the GRF outcomes, the first vertical peak increased by 0.91 N·kg$^{-1}$ , while vertical impulse decreased by 0.308 N·s·kg$^{-1}$ . The braking peak became more negative by 0.358 N·kg$^{-1}$ , and the propulsive peak increased by 0.223 N·kg$^{-1}$ (Table 3, Fig. 5). No statistically significant changes were observed for the remaining GRF outcomes.

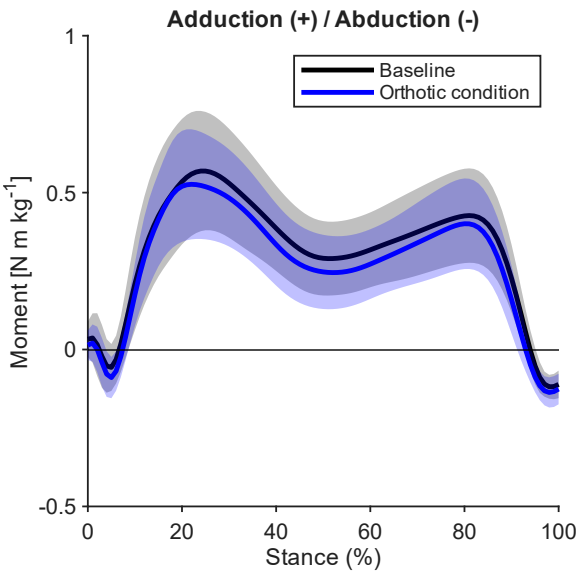



**Fig. 2.** Mean external knee adduction moment (KAM) during the stance phase of constant-speed walking. Baseline was assessed without the orthotic. The orthotic condition was assessed while wearing the orthotic after 6 weeks of regular use. Curves are time-normalised to 100% of stance and presented as mean ± SD.

## 4. Discussion

This study compared KAM-related measures and GRF variables between baseline walking without the orthotic and walking with a semi-rigid knee orthotic after six weeks of regular use in individuals with mKOA. During constant-speed walking, first-peak KAM, second-peak KAM, and KAAI were lower in the orthotic condition than at baseline, supporting the primary hypothesis. During self-selected-speed walking, participants walked faster and KAAI was lower, whereas first- and second-peak KAM did not differ significantly between conditions. The findings were consistent with the self-selected-speed hypothesis.

**Table 2**
KAM- and GRF-related variables during constant-speed walking (1.39 m/s). Baseline and orthotic-condition values are mean (SD). Paired differences were calculated as orthotic condition minus baseline and are reported with 95% confidence intervals. Mean paired differences are shown for paired *t*-tests (t), and Hodges–Lehmann estimates are shown for Wilcoxon signed-rank tests (W). Holm-adjusted p-values are reported for the three KAM-related outcomes; GRF outcomes and frontal-plane GRF lever arm were secondary and exploratory and were not adjusted for multiplicity. Effect sizes are reported as r-equivalents. GRF peaks refer to the respective GRF curves; lever-arm values were evaluated at the corresponding KAM peaks. * indicates p < 0.05. KAM: external knee adduction moment; KAAI: knee adduction angular impulse; GRF: ground reaction force.

| Variable | Baseline | Orthotic condition | Test | Paired difference (95% CI) | p-value | Effect size r |
|---|---|---|---|---|---|---|
| KAM first peak (N·m·kg$^{-1}$) | 0.58 (0.19) | 0.54 (0.17) | t | -0.040 (-0.074 to −0.005) | **0.045*** | 0.44 |
| KAM second peak (N·m·kg$^{-1}$) | 0.44 (0.15) | 0.41 (0.14) | W | -0.045 (-0.062 to −0.005) | **0.045*** | 0.47 |
| KAAI (N·m·kg$^{-1}$·s) | 0.19 (0.09) | 0.16 (0.08) | t | -0.021 (-0.038 to −0.005) | **0.045*** | 0.51 |
| GRF vertical first peak (N·kg$^{-1}$) | 11.29 (0.90) | 11.50 (0.86) | W | 0.155 (-0.058–0.429) | 0.153 | 0.29 |
| GRF vertical second peak (N·kg$^{-1}$) | 10.68 (0.86) | 10.77 (0.83) | W | 0.022 (-0.157–0.259) | 0.819 | 0.05 |
| GRF vertical impulse (N·kg$^{-1}$·s) | 4.75 (0.45) | 4.83 (0.38) | W | 0.109 (-0.001–0.193) | 0.056 | 0.39 |
| GRF braking peak (N·kg$^{-1}$) | -1.67 (0.22) | -1.81 (0.28) | t | -0.153 (-0.260 to −0.046) | **0.007*** | 0.53 |
| GRF propulsive peak (N·kg$^{-1}$) | 2.03 (0.28) | 2.09 (0.31) | t | 0.057 (-0.026–0.139) | 0.167 | 0.28 |
| GRF braking impulse (N·kg$^{-1}$·s) | -0.26 (0.04) | -0.27 (0.05) | t | -0.017 (-0.033 to −0.001) | **0.042*** | 0.41 |
| GRF propulsive impulse (N·kg$^{-1}$·s) | 0.27 (0.05) | 0.28 (0.05) | t | 0.014 (0.001–0.027) | **0.039*** | 0.42 |
| Frontal plane GRF lever arm at KAM first peak (cm) | 5.31 (1.56) | 5.37 (1.68) | t | 0.06 (-0.256–0.376) | 0.699 | 0.08 |
| Frontal plane GRF lever arm at KAM second peak (cm) | 4.22 (1.59) | 4.16 (1.44) | t | -0.05 (-0.388–0.282) | 0.746 | 0.07 |

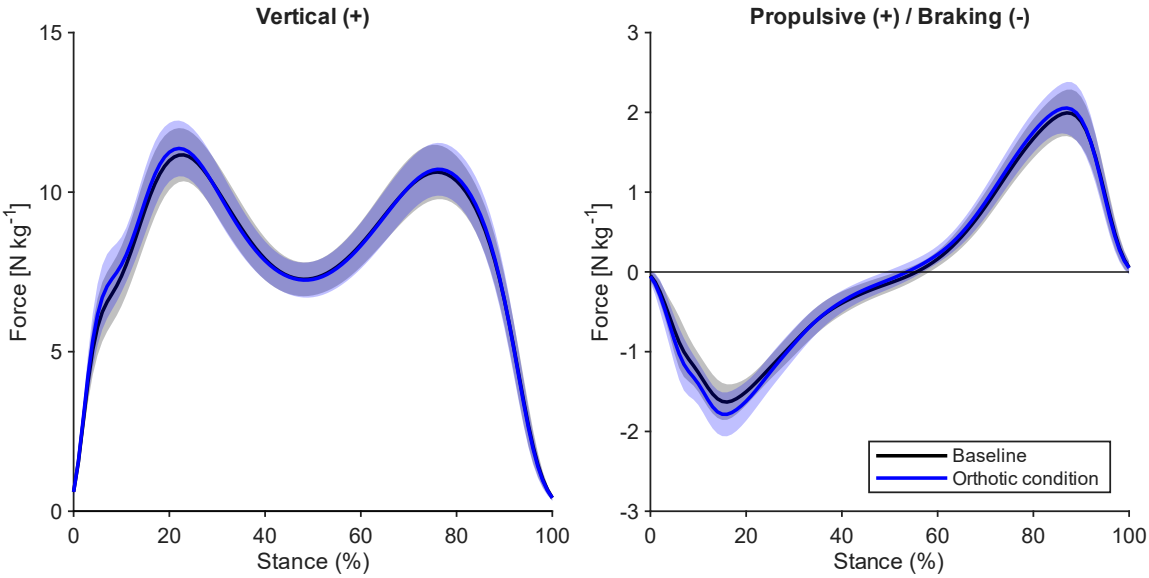



**Fig. 3.** Mean vertical and anterior–posterior ground reaction force (GRF) curves during the stance phase of constant-speed walking. Baseline was assessed without the orthotic. The orthotic condition was assessed while wearing the orthotic after 6 weeks of regular use. Curves are time-normalised to 100% of stance and presented as mean ± SD.

**Table 3**
KAM- and GRF-related variables during self-selected-speed walking. Baseline and orthotic-condition values are mean (SD). Paired differences were calculated as orthotic condition minus baseline and are reported with 95% confidence intervals. Mean paired differences are shown for paired *t*-tests (t), and Hodges–Lehmann estimates are shown for Wilcoxon signed-rank tests (W). Holm-adjusted p-values are reported for the three KAM-related outcomes; GRF outcomes and frontal-plane GRF lever arm were secondary and exploratory and were not adjusted for multiplicity. Effect sizes are reported as r-equivalents. GRF peaks refer to the respective GRF curves; lever-arm values were evaluated at the corresponding KAM peaks. * indicates $p < 0.05$. KAM: external knee adduction moment; KAAI: knee adduction angular impulse; GRF: ground reaction force.

| Variable | Baseline | Orthotic condition | Test | Paired difference (95% CI) | p-value | Effect size r |
|---|---|---|---|---|---|---|
| Walking speed ($m \cdot s^{-1}$) | 1.29 (0.21) | 1.49 (0.24) | t | 0.205 (0.095–0.315) | **< 0.001*** | 0.66 |
| KAM first peak ($N \cdot m \cdot kg^{-1}$) | 0.55 (0.18) | 0.55 (0.18) | t | 0.008 (-0.030–0.045) | 0.673 | 0.09 |
| KAM second peak ($N \cdot m \cdot kg^{-1}$) | 0.44 (0.16) | 0.42 (0.16) | t | -0.024 (-0.054–0.007) | 0.247 | 0.32 |
| KAAI ($N \cdot m \cdot kg^{-1} \cdot s$) | 0.20 (0.11) | 0.17 (0.09) | t | -0.030 (-0.050 to −0.010) | **0.014*** | 0.58 |
| GRF vertical first peak ($N \cdot kg^{-1}$) | 10.82 (0.71) | 11.73 (1.12) | t | 0.91 (0.517–1.274) | **< 0.001*** | 0.71 |
| GRF vertical second peak ($N \cdot kg^{-1}$) | 10.71 (0.71) | 10.79 (0.90) | W | 0.038 (-0.129–0.194) | 0.627 | 0.10 |
| GRF vertical impulse ($N \cdot kg^{-1} \cdot s$) | 5.07 (0.55) | 4.76 (0.45) | t | -0.308 (-0.492 to −0.125) | **0.002*** | 0.59 |
| GRF braking peak ($N \cdot kg^{-1}$) | -1.49 (0.28) | -1.85 (0.43) | t | -0.358 (-0.496 to −0.220) | **< 0.001*** | 0.74 |
| GRF propulsive peak ($N \cdot kg^{-1}$) | 1.94 (0.35) | 2.16 (0.41) | t | 0.223 (0.108–0.338) | **< 0.001*** | 0.64 |
| GRF braking impulse ($N \cdot kg^{-1} \cdot s$) | -0.25 (0.03) | -0.27 (0.05) | t | -0.017 (-0.034–0.001) | 0.061 | 0.38 |
| GRF propulsive impulse ($N \cdot kg^{-1} \cdot s$) | 0.28 (0.04) | 0.29 (0.05) | t | 0.011 (-0.003–0.026) | 0.126 | 0.31 |
| Frontal plane GRF lever arm at KAM first peak (cm) | 5.16 (1.55) | 5.35 (1.65) | W | 0.19 (-0.096–0.542) | 0.178 | 0.28 |
| Frontal plane GRF lever arm at KAM second peak (cm) | 4.26 (1.76) | 4.16 (1.56) | t | -0.10 (-0.416–0.215) | 0.516 | 0.14 |

### *4.1. Biomechanical effects during constant-speed walking*

The lower KAM-related values observed during constant-speed walking are broadly consistent with previous work on valgus unloader orthotics in mKOA. Systematic reviews generally conclude that these devices reduce KAM during gait [15,47,48], and primary studies have reported reductions in peak KAM and/or KAAI [49–51].

Although the observed reductions in first peak KAM (6.9%), second peak KAM (6.8%), and KAAI (15.8%) were smaller than many previously reported reductions, comparisons require caution. For example, the systematic review by Yan et al. [48] reported that traditional unloader orthotics reduced first peak KAM by 10.83–26.10%, second peak KAM by 9.80–33.89%, and KAAI by up to 36%. However, direct comparisons are limited by differences in orthotic construction, rigidity, valgus adjustment, mode of force application, KAM definitions and normalisation procedures, walking-speed conditions, disease severity and lower-limb alignment. This is particularly relevant because conventional KAM analyses do not always account for orthotic-induced moments [15]. Although previous studies have incorporated orthotic-generated forces into musculoskeletal modelling, for example using strap-force measurements relative to knee angle [31], the applied methods remain heterogeneous and are often insufficiently described [41,50,52]. The present analysis incorporated a participant-specific orthotic-induced moment, providing a more comprehensive estimate of frontal-plane knee loading. As a result, direct comparison with studies reporting conventional KAM alone or alternative approaches is limited. Within these constraints, the present findings are consistent with the broader evidence that walking with valgus-directed orthotics is associated with lower KAM-related measures. The 95% confidence intervals remained below zero for all three outcomes, supporting consistently lower KAM-related estimates, although the magnitude of these differences remains uncertain. Moreover, because higher KAM and KAAI have been associated with greater cartilage volume loss over time [53], even modest reductions in these parameters may be clinically relevant.

The GRF findings provide additional context for the changes in KAM-related measures. No clear differences were observed in the vertical GRF variables during constant-speed walking, suggesting that the lower KAM-related measures were not simply associated with a general

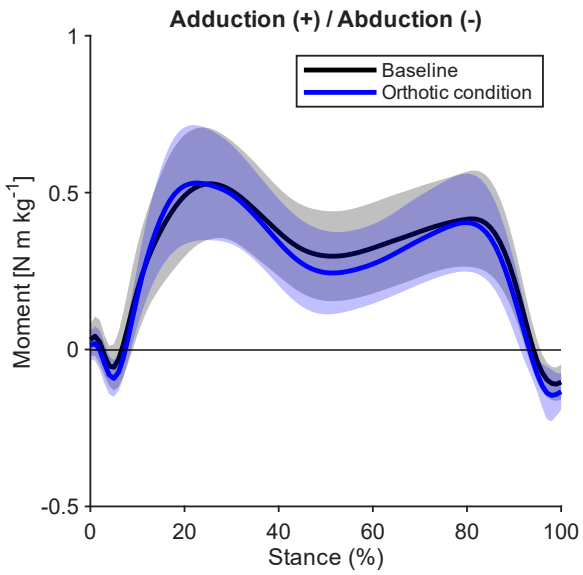



**Fig. 4.** Mean external knee adduction moment (KAM) during the stance phase of self-selected-speed walking. Baseline was assessed without the orthotic. The orthotic condition was assessed while wearing the orthotic after 6 weeks of regular use. Curves are time-normalised to 100% of stance and presented as mean ± SD.

reduction in vertical limb loading. Another important determinant of KAM is the frontal-plane GRF lever arm [6], and previous studies of valgus knee orthotics have reported KAM reductions accompanied by a shortening of this lever arm [50]. However, the additional post hoc analysis in the present study showed no significant differences in the frontal-plane GRF lever arm at either KAM peak. Thus, the lower peak KAM values occurred without a systematic reduction in either vertical GRF or the frontal-plane GRF lever arm. This pattern suggests that the counteracting abduction moment generated by the orthotic was an important contributor to the observed KAM reductions, which is consistent with previous modelling work demonstrating a substantial role of the direct orthotic abduction moment in medial knee unloading [54].

The more negative braking peak and the greater magnitudes of the braking and propulsive impulses indicate altered anterior-posterior force generation. One possible interpretation is that these changes reflect altered gait adaptations, as individuals with knee osteoarthritis may modify their gait to limit discomfort and joint loading [55,56]. This interpretation is also compatible with the reduced walking pain previously reported in the present cohort [21]. However, greater braking and propulsive forces should not necessarily be interpreted as beneficial, as they also represent greater anterior-posterior external force demands. The underlying gait strategy and the implications of these changes for knee joint loading remain uncertain because sagittal-plane knee kinetics, joint kinematics, and muscle activation were not analysed.

### 4.2. *Complementary findings during self-selected-speed walking*

Participants walked 15.5% faster in the orthotic condition than at baseline, consistent with the direction of the functional and symptomatic improvements reported in this cohort [21]. In the previous analysis, the same participants increased their 6-minute walk distance by 24.5 m (approximately 5%), while pain during walking decreased from 2.84 to 1.54 and pain during stair climbing from 2.97 to 1.74 on a 0–10 VAS [21]. The increase in 6-minute walk distance was similar in magnitude to the approximately 20 m change proposed as a small meaningful improvement in older adults with mobility limitations [57], although this threshold was not derived specifically from individuals with knee OA. Perrot et al. reported a minimal clinically important improvement of approximately 1 point on a 0–10 scale for pain on movement in individuals with painful knee or hip osteoarthritis [58]. Although the applicability of these thresholds to the present cohort and across different pain situations remains uncertain, these previously reported functional and symptomatic changes provide clinical context for the higher self-selected walking speed observed in the present analysis. Additional improvements were reported for KOOS activities of daily living, sport and leisure activities, and quality of life [21].

Gait speed is known to influence KAM-related measures [25]. Faster walking generally tends to increase peak KAM, whereas impulse-based measures such as KAAI may decrease due to the associated shorter stance duration [23]. Therefore, the lower KAAI observed in the orthotic condition during self-selected walking should be interpreted cautiously, as the contribution of the higher walking speed cannot be distinguished

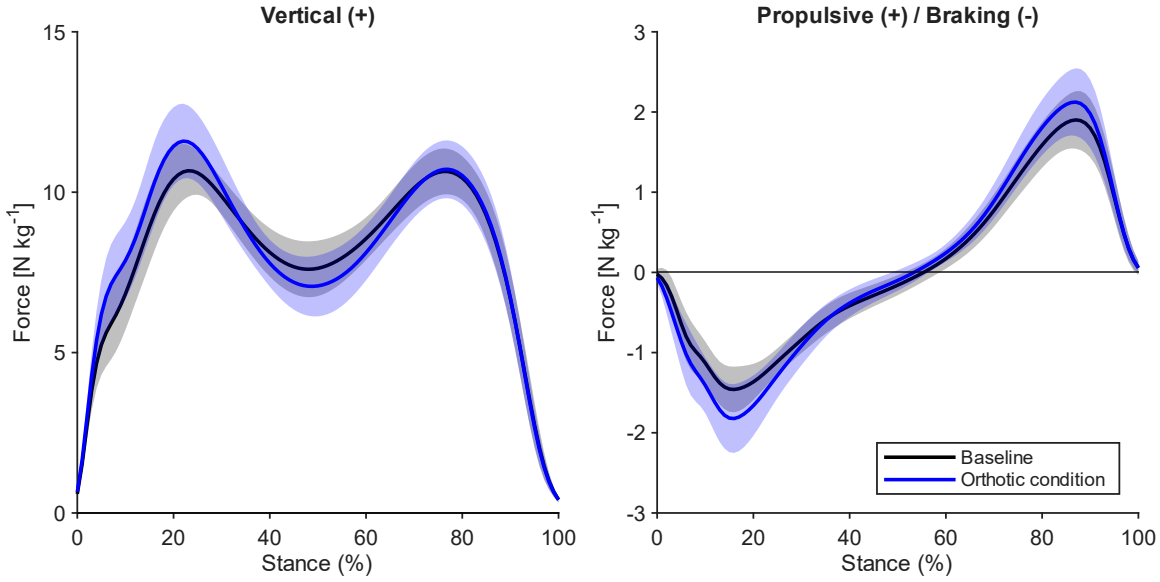



**Fig. 5.** Mean vertical and anterior–posterior ground reaction force (GRF) curves during the stance phase of self-selected-speed walking. Baseline was assessed without the orthotic. The orthotic condition was assessed while wearing the orthotic after 6 weeks of regular use. Curves are time-normalised to 100% of stance and presented as mean ± SD.

from a potential unloading contribution of the orthotic. In contrast, the constant-speed condition controlled for walking speed between assessments and therefore allowed evaluation of KAAI independent of changes in self-selected gait speed. With regard to peak KAM, first- and second-peak KAM did not show clear increases despite the higher self-selected walking speed. The additional post hoc analysis showed no significant differences in the frontal-plane GRF lever arm at either KAM peak, suggesting that a systematic shortening of the lever arm was not the primary mechanism underlying this response. Together, these findings are compatible with a possible unloading contribution of the orthotic during faster self-selected walking.

The GRF response to the higher self-selected walking speed was variable-specific, with the first vertical GRF peak increasing clearly (8.4%), whereas the second vertical peak changed only minimally (0.7%). This pattern is consistent with previously described speed-related GRF behaviour, in which the early vertical GRF peak is more responsive to walking speed than the later peak [59]. In addition, the lower vertical GRF impulse and higher braking and propulsive GRF peaks resemble previously reported speed-related kinetic changes [24]. The coexistence of faster walking, these accompanying GRF changes, and no clear increase in peak KAM may reflect compensatory biomechanical mechanisms that mitigated speed-related increases in frontal-plane knee loading and might help explain the functional and symptomatic improvements previously reported in this cohort [21]. Other gait adaptations, such as changes in foot progression angle, lower limb kinematics, or centre of pressure progression, may also have contributed but were not analysed separately. Therefore, the underlying mechanisms and their relationship with the previously reported clinical changes remain uncertain.

### 4.3. Clinical implications

These findings should be interpreted in light of the fact that KAM and KAAI are biomechanical surrogate measures of medial knee loading, not direct clinical outcomes [7,8]. Although higher dynamic medial knee loading, particularly KAAI, has been associated with subsequent cartilage volume loss [53], no validated minimal clinically important difference has been established for KAM-related measures. Nevertheless, the observed reductions of 6.9–15.8%, accompanied by moderate-to-large effect sizes, indicate a measurable biomechanical response during constant-speed walking. These findings occurred alongside the symptomatic and functional improvements previously reported in the same cohort [21], providing context for their potential clinical relevance. However, individual-level associations between biomechanical and clinical changes were not assessed.

The magnitude of the reductions was comparable to that reported for other conservative interventions, such as sensor-based gait retraining, which reduced first-peak KAM by approximately 15% [60]. This comparison is intended only to contextualise the magnitude of the biomechanical changes and does not imply equivalent clinical benefit, as the interventions differ in their mechanisms, treatment demands, target populations, and accompanying clinical outcomes.

From a clinical perspective, the evaluated semi-rigid orthotic may be considered as an adjunct for individuals with symptomatic medial tibiofemoral osteoarthritis and varus alignment. The present findings are most directly applicable to individuals with relatively preserved ambulatory function who are able to use the orthotic regularly. However, the group-level findings do not imply that all individuals will respond similarly or establish criteria for identifying responders. Orthotic fitting and valgus adjustment should therefore be individualised, and treatment response should be evaluated according to comfort, adherence, pain, walking function, and participation in daily activities. Consistent with current recommendations for individualised and multicomponent knee osteoarthritis management [61], the orthotic should be considered as one possible component of care.

The mechanisms associated with clinical responses to semi-rigid knee orthotics remain incompletely understood. The combination of valgus-directed structural elements and a sleeve-like component suggests that responses may involve interacting biomechanical, neurosensory, neuromuscular, and behavioural pathways rather than frontal-plane unloading alone [17]. These pathways were not assessed in the present study, and their relative contributions cannot be determined. Future studies should combine biomechanical, neuromuscular, and patient-reported outcomes to examine which mechanisms are associated with individual clinical responses and whether they differ between orthotic designs.

### 4.4. Limitations

Several limitations should be considered. First, the orthotic-induced abduction moment was derived from quasi-static bench testing rather than measured dynamically during gait. This approach does not capture the time-varying orthotic behaviour during gait, including potential effects of loading rate and cyclic loading, changes in knee flexion and frontal-plane position, or orthotic-soft tissue interaction. However, the moment-angle relationship was relatively flat within the varus-alignment range of most participants, suggesting that small frontal-plane variations would result in only modest changes in the estimated moment (see Fig. 1B). Including the orthotic moment nevertheless provided a more comprehensive representation than conventional KAM analysis alone, as KAM may remain unchanged unless the brace moment is considered explicitly [54]. Future studies should assess whether bench-derived orthotic moments are comparable to those measured dynamically during gait, although such measurements require dedicated instrumented orthotic setups [52].

Second, varus alignment was determined using laser-based anthropometry, and knee markers were placed on the orthotic, potentially reducing alignment and kinematic precision. Both procedures were, however, applied consistently across participants and reflected the practical constraints of gait assessment while wearing an orthotic.

Third, no immediate post-fitting biomechanical assessment with the orthotic was performed, and no no-orthotic condition was included at the 6-week follow-up. Consequently, the mechanical contribution of wearing the orthotic cannot be separated from adaptations to regular use, repeated testing, symptom variation, or other time-related influences. The findings should therefore be interpreted as differences between baseline gait without the orthotic and gait while wearing the orthotic after 6 weeks of regular use, rather than as effects attributable solely to the orthotic or to adaptation over time. Assessment after regular use may nevertheless have reduced effects of initial unfamiliarity and provided a more clinically representative evaluation of orthotic walking [62].

Fourth, although the frontal-plane GRF lever arm was assessed in an additional exploratory post hoc analysis, muscle activation, sagittal-plane knee moments, tibiofemoral contact forces, and specific gait adaptations such as changes in foot progression angle or lower-limb kinematics were not evaluated. Therefore, the underlying mechanisms of the observed KAM pattern and their implications for overall knee joint loading remain uncertain. Future studies combining electromyography, detailed kinematic analyses, and musculoskeletal estimates of knee contact forces may provide a more comprehensive assessment of these mechanisms.

Finally, this study was an additional biomechanical analysis of a previously established cohort. No separate a priori sample-size calculation was performed for the present two-time-point secondary analysis, as the original sample-size calculation was based on the three-time-point design of the parent study. Although the sample size was comparable to previous biomechanical knee-orthotic studies [31,63], it may have limited the precision of the estimates and the sensitivity to smaller between-condition differences. The selected mKOA cohort also limits generalisability; larger and more heterogeneous samples are therefore needed.

## 5. Conclusion

In individuals with mKOA, walking with the semi-rigid orthotic after 6 weeks of regular use was associated with lower first peak KAM, second peak KAM, and KAAI during constant-speed walking compared with baseline walking without the orthotic. During self-selected-speed walking, participants walked faster and KAAI was lower, while the estimated changes in peak KAM showed no differences between conditions. These findings are consistent with a potential contribution of the orthotic to frontal-plane unloading; however, the immediate mechanical effect of wearing the orthotic cannot be separated from adaptation to regular use, walking-speed differences, and other time-related influences. The biomechanical findings complement the symptomatic and functional improvements previously reported in the same cohort, although associations between biomechanical and clinical responses remain to be established. Further research could examine relationships between biomechanical changes and patient-reported outcomes and determine the relative contributions of biomechanical, neuromuscular, sensory, and behavioural mechanisms.

## CRediT authorship contribution statement

**Pauline Göbel:** Writing – original draft, Visualization, Software, Formal analysis. **Batın Yılmazgün:** Writing – review & editing, Resources, Investigation. **Stefan Sell:** Writing – review & editing, Funding acquisition, Conceptualization. **Thorsten Stein:** Writing – review & editing, Conceptualization, Funding acquisition. **Bernd J. Stetter:** Supervision, Project administration, Methodology, Investigation, Conceptualization.

## Ethics declaration

Written informed consent to take part in the study and to publish the article has been obtained from all participants or their legal representatives. The privacy rights of participants have been observed.

This study was performed in compliance with relevant laws, regulatory frameworks and guidelines where the research took place. This study was approved by the Ethics Committee of the Karlsruhe Institute of Technology (Project description: Biomechanische Evaluation einer Kniebandage für Patienten mit medialer Gonarthrose, date of approval 12 March 2020).

## Ethics statement

The research involving human participants received approval from the Ethics Committee of the Karlsruhe Institute of Technology. Written informed consent was provided by all participants.

## Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used ChatGPT (OpenAI) to improve the language, readability, and phrasing of the manuscript. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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## Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Bernd J. Stetter reports financial support provided by Bauerfeind AG. Bernd J. Stetter reports a relationship with Bauerfeind AG that includes: employment. Stefan Sell reports a relationship with Bauerfeind AG that includes: consultancy. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Data availability statement

The dataset created for this study can be obtained by contacting the corresponding author.

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