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Original article

The immediate effect of a soft knee brace on dynamic knee instability in persons with knee osteoarthritis

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Abstract

Objectives. Wearing a soft knee brace has been shown to reduce self-reported knee instability in persons with knee OA. There is a need to assess whether a soft knee brace has a beneficial effect on objectively assessed dynamic knee instability as well. The aims of the study were to evaluate the effect of a soft knee brace on objectively assessed dynamic knee instability and to assess the difference in effect between a non-tight and a tight soft knee brace in persons with knee OA.

Methods. Thirty-eight persons with knee OA and self-reported knee instability participated in a laboratory study. A within-subject design was used comparing no brace vs brace and comparing a non-tight vs a tight brace. The primary outcome measure was dynamic knee instability, expressed by the perturbation response (PR). The PR reflects deviation in the mean knee varus–valgus angle during level walking after a controlled mechanical perturbation. Linear mixed-effect model analysis was used to evaluate the effect of a brace on dynamic knee instability.

Results. Wearing a brace significantly reduced the PR compared with not wearing a brace ($B = -0.16$, $P = 0.01$). There was no difference between a non-tight and a tight brace ($B = -0.03$, $P = 0.60$).

Conclusion. This study is the first to report that wearing a soft knee brace reduces objectively assessed dynamic knee instability in persons with knee OA. Wearing a soft brace results in an objective improvement of knee instability beyond subjectively reported improvement.

Trial registration. Nederlands Trial register (trialregister.nl) NTR6363

Key words: knee, osteoarthritis, brace, orthotics, knee instability

Rheumatology key messages

- Wearing a soft knee brace reduces dynamic knee instability beyond previously reported subjective improvement in persons with knee OA.
- A non-tight and tight brace provided the same level of dynamic knee stability in persons with knee OA.

Introduction

Symptomatic knee joint instability, experienced as episodes of knee buckling or giving way, has been reported in the majority (>60%) of persons with knee OA [1, 2] and is associated with activity limitations [3, 4]. Various interventions may be applied to reduce knee instability, including wearing a soft knee brace. It has been shown that a soft knee brace indeed reduces self-reported knee instability in persons with knee OA [5, 6]. Although this is an important finding, self-reported outcomes measure a different construct from the physical measures and might be susceptible to bias [7]. Evaluation of objectively assessed knee instability during gait (dynamic knee instability) could strengthen the evidence for application of a soft knee

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brace to reduce knee instability in persons with knee OA. However, to our knowledge, no evidence exists to show that a soft knee brace reduces dynamic knee instability.

Knee instability is defined as the loss of ability to maintain a position or control movements of the knee joint under differing external loads [8]. Several attempts have been made to quantify knee instability. These attempts involved measuring knee varus–valgus movement during level walking and calculating the Lyapunov exponent; these methods evaluate naturally occurring movements of the knee [9–11]. Applying an external perturbation during gait and assessing the resulting deviation of the knee joint provides an alternative objective measure of knee instability: persons who have difficulty maintaining a position or control of movements of the knee in daily life constitute a relevant experimental control and are expected to show deviation of the knee joint after application of the perturbation. The perturbation response (PR) reflects the deviation of the knee joint after typically occurring perturbations (e.g. trip, slip or sideways push) in which the knee is challenged to stay stable under well-controlled laboratory conditions [12, 13]. As excessive knee frontal plane motion during weight-bearing activity has often been suggested to reflect knee instability in persons with knee OA [4, 14, 15], the present study used the PR in the frontal plane (derived from the varus–valgus angle) as an objective measure of dynamic knee instability.

It has been suggested that a soft knee brace improves knee joint stability via stimulation of cutaneous mechanoreceptors [16]. The action of a soft brace on cutaneous mechanoreceptors might depend on how tight a soft brace fits the knee [17]. As a consequence, the tightness of a soft brace is expected to influence its effects [17]. Previously we evaluated the effect of tightness of a soft brace on self-reported knee instability [6]. The results showed that wearing a soft brace reduced self-reported knee instability, however, there was no difference between a non-tight and a tight soft brace [6]. The PR as a reflection of dynamic knee instability can be a more sensitive measure to detect differences between the two types of braces.

This study aimed to evaluate the effect of a soft knee brace on dynamic knee instability, as expressed by the PR, and to assess the difference in effect between a non-tight and a tight knee brace in persons with knee OA. We hypothesized that wearing a soft knee brace reduces dynamic knee instability.

Methods

Study design

In this single-session lab-experimental study, a within-subject design was used comparing not wearing a soft brace with wearing a soft brace and comparing wearing a non-tight brace with wearing a tight brace. The order of the non-tight and tight brace was randomized, using a computer-generated random sequence prior to the study. Participants were blinded to the type of brace by

informing them that the study was a comparison of two different braces without mentioning specific differences.

Participants

Participants were recruited through telephone-based screening between August 2015 and April 2016. Inclusion criteria for the present study were diagnosis of knee OA according to the clinical ACR criteria [18], age 50–80 years and the presence of self-reported knee instability in the past 3 months. Self-reported knee instability was defined as at least one episode of buckling, shifting or giving way of the knee [19]. Exclusion criteria for the present study were total knee replacement and/or inflammatory arthritis (including RA, crystal arthropathy, septic arthritis and SpA), radiographic patellofemoral joint OA and the presence of comorbidity resulting in severe activity limitations (i.e. a neurological condition resulting in difficulties in walking). Persons with patellofemoral joint OA were excluded because the soft brace used in the study was not designed for this group of persons. The brace did not have a patellar opening, which could have applied too much pressure in the patellofemoral compartment, possibly leading to pain.

All participants provided written informed consent according to the Declaration of Helsinki. Ethics approval was obtained from the Medical Research Ethics Committee of the VU University Medical Center, Amsterdam (METC 2015.105).

Interventions

A commercially available soft knee brace (GENUTEX A2, Human I, Bleiswijk, The Netherlands) was used. A tight brace was defined as one fitted based on shank and thigh circumferences measured according to instructions provided by the distributor (standard fit). A non-tight brace was defined as one size larger than a tight brace. A full description of the fitting and positioning of the brace was provided in our previous study [6].

Procedure

Participants walked, both without and with the brace, on a treadmill, which is integrated in the GRAIL system (Motekforce Link, Amsterdam, The Netherlands). The GRAIL system is made up of a dual-belt instrumented treadmill placed in a virtual reality environment.

Walking on the treadmill was initially performed without wearing a brace. Participants walked wearing a safety harness that provided no body weight support. Participants had a familiarization session on the treadmill lasting at least 1 min. Comfortable walking speed was determined during the familiarization session by incrementing the speed slowly until the speed was agreed upon by the participant. Following the familiarization session, participants were subjected to two tasks: level walking for 2 min and walking with mechanical perturbations on the treadmill. Participants were verbally informed about the mechanical perturbations prior to the task. Mechanical perturbations on the treadmill comprised five lateral and five medial translations (2 cm displacements, peak

velocity 10 cm/s) of the treadmill belts occurring during 20–50% of the gait cycle of the affected knee [20]. The affected knee was defined as the one indicated most painful by the participant or the knee of the dominant leg in case of similar symptoms between knees. Treadmill and perturbation speed were controlled using D-Flow software (Motekforce Link) [21]. Perturbation timing was controlled and based on real-time estimation of heel strikes [22]. The time interval between perturbations was randomly determined to be between 10 and 15 strides. Subsequently participants were randomized to receive a non-tight or a tight brace and the whole procedure (i.e. the two tasks) was repeated while wearing a brace. After a 30 min rest, the procedure crossed over to the second part of the assessment with a second baseline trial with no brace and an intervention trial with the other type of a soft brace (tight or non-tight). The potential confounding effect of fatigue and learning effects on the comparison between non-tight and tight braces was controlled by counterbalancing the order of the brace type.

During the walking trials, 3D movement of the lower legs, pelvis and trunk were captured via markers on anatomical landmarks [23] at 100 Hz using a motion-capture system (Vicon, Oxford, UK). The following locations were used for anatomical markers: 1st, 2nd and 5th metatarsal head; calcaneus (rear aspect); medial and lateral malleoli; tibial tuberosity; head of the fibula; medial and lateral epicondyles; anterior and posterior superior iliac spine; navel; xyphoid process; jugular notch; 7th cervical vertebrae and 10th thoracic vertebrae. Additional markers were affixed on each segment as necessary for tracking purposes. Force plate data recorded at 1000 Hz were used to determine the stance phase of the gait cycle and timing of perturbations (Motekforce Link).

Outcome measure

Dynamic knee instability was expressed by the PR [12], a measure derived from the gait sensitivity norm [13]. PR values are positive values and reflect absolute changes. Lower PR values indicate less deviation in the mean varus–valgus angle during the stance phase of the affected knee due to a controlled perturbation. The stance phase was defined as the phase of the gait cycle from initial contact to toe-off. PR was calculated with Equation (1):

$$PR = \text{abs} \left(\frac{g_i(k) - g_i^*}{\sigma g_i^*} \right), \quad (1)$$

where $g_i(k)$ is the mean varus–valgus angle of a perturbed gait cycle, g_i^* is the mean varus–valgus angle of all unperturbed gait cycles from a baseline level walking trial and σg_i^* is the s.d. of g_i^* .

We used data from the perturbation that was assumed to challenge (i.e. increase) dynamic malalignment of the knee joint during the stance phase of the gait cycle. To achieve an increase in malalignment, we selected the direction of the perturbation based on the dynamic malalignment at baseline: if the affected knee had a valgus malalignment during baseline level walking, for $g_i(k)$, the

mean varus–valgus angle was used from the laterally directed perturbation; whereas in the case of varus malalignment, the mean varus–valgus angle was used from the medially directed perturbation. Valgus dynamic malalignment was defined as an average varus–valgus angle $<0^\circ$ ($<180^\circ$), with varus $\geq 0^\circ$ ($\geq 180^\circ$), during the stance phase of all gait cycles during the baseline level walking trial. A lateral/medial direction of a perturbation was defined in relation to the affected knee. To normalize for physiological variability during unperturbed walking in humans, $g_i(k) - g_i^*$ is divided by σg_i^* [13].

Data processing

To obtain the PR, the varus–valgus angles of the affected knee (perturbed leg) were calculated from marker data using custom-made software (BodyMech, www.body-mech.nl, Matlab-based), with anatomical coordinate systems defined according to Cappozzo *et al.* [23]. Marker position data were filtered at 6 Hz to remove high-frequency artefacts. Force data were filtered at 10 Hz with a second-order bi-directional filter. A force threshold of 25 N was used to establish gait events. All data were time normalized to 100% of the gait cycle (from initial contact to initial contact) [24].

Other measures

Participants' demographic and clinical characteristics were recorded prior to testing and included age, gender, BMI, duration of symptoms, average knee pain last week [25], muscle strength assessed isokinetically (Nm/kg), knee OA radiographic severity [Kellgren and Lawrence (KL) grade] [26] and WOMAC [27, 28]. A full description of these measures was provided in our previous study [6].

Statistical analysis

Descriptive statistics were used to characterize the study population. Numbers (percentages) were used for categorical variables and mean (s.d.) for continuous variables. Prior to the statistical analysis, the PR was checked for normality with Shapiro–Wilk and Kolmogorov–Smirnov tests. The PR was obtained for the affected knee and data from this knee were used in the statistical analysis. Four comparisons were analysed: brace vs no brace, tight brace vs no brace (i.e. baseline before tight), non-tight brace vs no brace (i.e. baseline before non-tight) and non-tight brace vs tight brace. For the comparison between brace vs no brace, data from the first and the second parts of the assessments were collapsed. Linear mixed model analysis for repeated measurements within participants was used with the PR as the dependent variable. This allowed us to assess the change in PR using data from all four assessments, removing the effect of change over time, while adjusting for within-subject correlated measures [29]. No covariates were included in the models because addition of a covariate to a repeated measures analysis would not alter the main effects of a within-subject factor for this particular study design (e.g. age, gender, etc. are the same at each data point) [30]. Statistical significance was accepted at $P < 0.05$.

All analyses were performed using SPSS software, version 22.0 (IBM, Armonk, NY, USA).

Results

Demographics and clinical characteristics of the participants are shown in Table 1. Thirty-eight persons with knee OA and self-reported knee instability participated in the study. The participants had a mean age of 66.4 years (s.d. 9.3), a mean BMI of 29.1 kg/m² (s.d. 5.0) and 24 (62.3%) were women.

The results of Shapiro–Wilk and Kolmogorov–Smirnov tests indicated that the PR was not normally distributed ($P < 0.05$), hence a square root transformation of the PR was applied prior to conducting the statistical analyses. In order to be able to interpret the results of the regression analysis, the data were back transformed.

Wearing a soft knee brace significantly reduced the PR ($B = -0.16$, $P = 0.010$; Table 2, column 2) compared with not wearing the brace. There was no significant difference in the PR when wearing a tight brace compared with not wearing a tight brace ($B = -0.10$, $P = 0.35$; Table 2, column 3). Wearing a non-tight brace significantly reduced the PR compared with not wearing a non-tight brace ($B = -0.21$, $P = 0.003$; Table 2, column 4). The difference in the effect between a non-tight and tight brace was not significant ($B = -0.03$, $P = 0.6$; Table 2, column 5).

Across all persons, the PR mean value was 0.48 and 0.32 when not wearing or wearing the brace, respectively. This corresponds to a reduction of 33%. In persons with dynamic varus malalignment, the PR mean value was 0.50 and 0.34 when not wearing or wearing the brace, respectively (a reduction of 32%). In persons with dynamic valgus malalignment, the PR mean value was 0.47 when not wearing the brace and 0.32 when wearing the brace (a reduction of 32%). Complete biomechanical characteristics by conditions are presented in Table 3. Mean waveforms of the knee varus–valgus angle during level and perturbed walking for persons with dynamic varus and valgus malalignment are presented in Fig. 1.

Discussion

This study is the first to report that wearing a soft knee brace reduces objectively assessed dynamic knee instability in persons with knee OA. The influence of externally applied perturbations on knee stabilization strategies in persons with knee OA has been reported in some studies, with a focus on muscle activity [31–33]. In contrast to these studies, we investigated deviations in knee frontal plane movement, which is potentially more relevant from a clinical perspective as it has been associated with several clinical symptoms in persons with knee OA [34–36]. Wearing the brace resulted in a reduction of 33% in dynamic knee instability compared with not wearing the brace. We observed similar effects for persons with varus malalignment and for persons with valgus malalignment.

The PR takes into account absolute changes in angles and represents actual deviations: an increase or a decrease. To better understand the absolute changes,

TABLE 1 Descriptive statistics of the study participants ($n = 38$)

Variable	Value
Age, years	66.4 (9.3)
Female, n (%)	24 (62.3)
BMI, kg/m ²	29.1 (5.0)
Duration of symptoms, years	12.7 (10.4)
Pain last week (NRS) (0–10)	4.5 (2.0)
WOMAC, pain (0–20)	8.3 (3.8)
WOMAC, stiffness (0–8)	4.4 (1.5)
WOMAC, physical function (0–68)	31.3 (12.3)
WOMAC, total score (0–96)	44.1 (16.7)
Muscle strength, Nm/kg	0.91 (0.32)
Walking speed on the treadmill, m/s	0.76 (0.25)
KL grade, n (%)	
0, none	4 (10.8)
1, doubtful	14 (37.8)
2, mild	8 (21.6)
3, moderate	8 (21.6)
4, severe	3 (8.1)
Self-reported knee instability <3 months, n (%)	
Rarely, 1–2 times	14 (36.8)
Regularly, 3–4 times	16 (42.1)
Very often, >4 times	8 (21.1)
Dynamic malalignment at baseline, n (%)	
Varus	18 (47.3)
Valgus	20 (52.7)
PR at baseline stratified for malalignment, mean (range)	
Varus malalignment	0.63 (0.02–1.84)
Valgus malalignment	0.52 (0.05–1.63)

Values are mean (s.d.) unless stated otherwise. K&L: Kellgren & Lawrence; NRS: numeric rating scale; PR: Perturbation Response, stratified for participants with varus and valgus dynamic knee malalignment.

evaluation of mean knee angles stratified for baseline dynamic knee malalignment need to be considered (Fig. 1). An increase in the varus angle during mid-stance of the perturbed gait cycle was seen in participants with dynamic varus knee malalignment while not wearing the brace. This pattern was not observed while wearing the brace (Fig. 1A). In persons with dynamic valgus malalignment, an increase in the valgus angle during the entire stance phase of the perturbed gait cycle was observed while not wearing the brace. However, when wearing the brace, the increase in the varus–valgus angle in these participants was less pronounced (Fig. 1B).

These results may have clinical implications. Measures of varus/valgus movement have been associated with knee pain and stiffness [34, 35], lack of confidence in the knees [37], the knee adduction moment [38] and structural progression of the disease [39, 40]. Thus, theoretically, wearing a soft brace could potentially reduce symptoms and knee OA progression by limiting the frontal plane movement of the knee in the presence of external perturbations during daily life of persons with knee OA. However, it is not clear whether the observed effects in kinematics caused by the brace are sufficient to yield clinical benefits. Since this is the first study in persons with

TABLE 2 Dynamic knee instability (PR)

Outcome	Brace vs no brace		Tight brace vs no brace		Non-tight brace vs no brace		Non-tight vs tight brace	
	B (95% CI)	P-value	B (95% CI)	P-value	B (95% CI)	P-value	B (95% CI)	P-value
PR	-0.16 (-0.25, -0.05)	0.010*	-0.10 (-0.26, 0.05)	0.35	-0.21 (-0.32, -0.07)	0.003*	-0.04 (-0.14, 0.07)	0.60

*Significant at $P < 0.05$.

TABLE 3 Biomechanical characteristics of the study participants by the conditions and dynamic knee malalignment

Outcomes	No brace ^a	Brace ^b	No brace	Tight brace	No brace	Non-tight brace
All participants ($n=38$)						
PR ^c	0.48 (0.4)	0.32 (0.2)	0.45 (0.4)	0.35 (0.2)	0.52 (0.2)	0.31 (0.2)
Varus/valgus, level walk, ° ^d	-1.02 (5.5)	-1.27 (5.5)	-1.04 (5.4)	-1.22 (5.5)	-1.01 (5.7)	-1.32 (5.5)
Varus/valgus, perturbed walk, ° ^e	-1.04 (5.7)	-1.16 (5.6)	-1.22 (5.6)	-1.20 (5.7)	-0.86 (5.9)	-1.12 (5.7)
Participants with varus dynamic malalignment ($n = 18$)						
PR	0.50 (0.4)	0.34 (0.2)	0.49 (0.4)	0.33 (0.2)	0.51 (0.3)	0.34 (0.2)
Varus/valgus, level walk, °	4.07 (2.3)	3.42 (3.0)	3.88 (2.3)	3.24 (3.2)	4.26 (3.0)	3.60 (2.8)
Varus/valgus, perturbed walk, °	4.36 (2.0)	3.70 (3.3)	3.97 (2.2)	3.47 (3.5)	4.74 (2.6)	3.93 (3.0)
Participants with valgus dynamic malalignment ($n = 20$)						
PR	0.47 (0.4)	0.32 (0.2)	0.42 (0.3)	0.35 (0.2)	0.51 (0.4)	0.29 (0.2)
Varus/valgus, level walk, °	-5.0 (3.5)	-4.94 (3.9)	-4.97 (3.4)	-4.79 (4.2)	-5.03 (3.6)	-5.08 (3.8)
Varus/valgus, perturbed walk, °	-5.26 (3.7)	-4.96 (4.0)	-5.39 (3.7)	-4.95 (4.1)	-5.14 (3.8)	-4.97 (3.9)

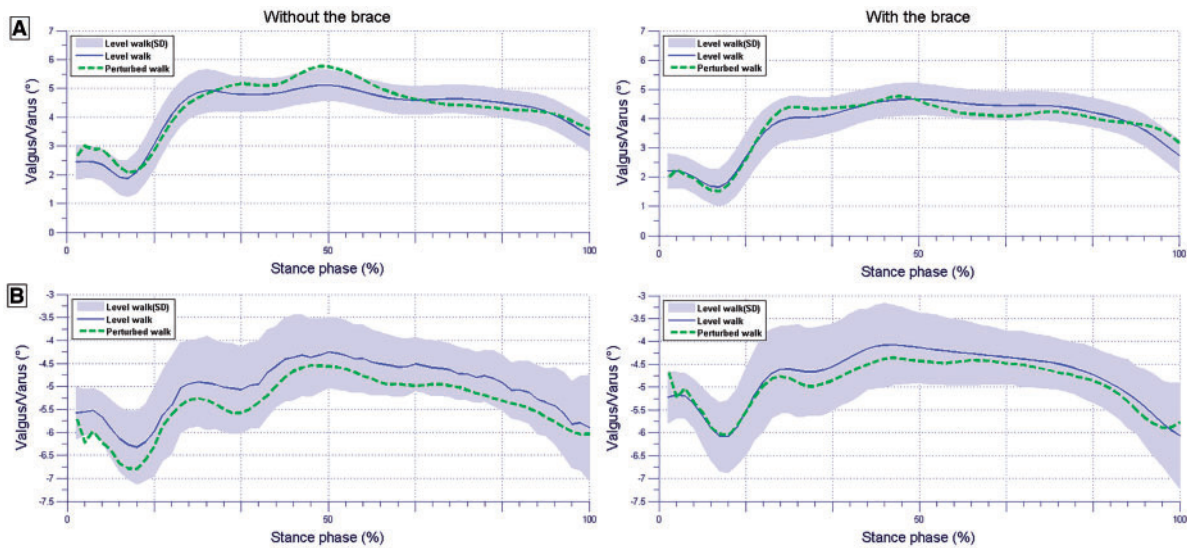
Values are presented as mean (s.d.). ^aAveraged data from the control condition before wearing a tight and before wearing a non-tight brace. ^bAveraged data from the condition of wearing a tight and wearing a non-tight brace. ^cPerturbation response: absolute deviation in varus/valgus angle standardized to the mean (s.d.) varus/valgus angle during baseline level walking. ^dMean varus–valgus angle during level walking, that is, actual angle in degrees. ^eMean varus–valgus angle during perturbed walking, that is, actual angle in degrees.

knee OA to examine the effect of soft bracing on dynamic knee instability, there are no directly comparable results in the literature. Longitudinal studies outside the laboratory are needed to determine whether the observed effect will also have clinical implications in the daily lives of persons with knee OA. Before translating the results into a clinical practice, the next study would be to test the effect of a soft brace on clinical outcomes outside the gait laboratory in a randomized controlled trial.

Currently the international guidelines are not homogeneous regarding the use of soft knee braces in knee OA [41–43]. The discrepancy is based on a lack of strong evidence existing at that time. However, the effectiveness of a soft knee brace on pain and physical function has been shown in a recent meta-analysis [44]. Moreover, soft knee braces have shown efficacy in improving several knee function-related parameters that might be generalized to the daily lives of persons with knee OA, including self-reported knee instability [5, 6], dynamic knee instability in this study and confidence in the knees [6]. An update of the guidelines is recommended based on these findings.

The mechanisms underlying the observed effect are not completely clear. While an unloading brace elicits effects by providing a varus/valgus moment to correct the malalignment of the knee joint [45], a soft brace is suggested to act through sensorimotor mechanisms [44]. Soft braces are thought to induce cutaneous stimuli augmenting

proprioceptive feedback [16], resulting in increased muscle activity that limits knee movements in response to perturbations. Moreover, it has been reported that the intensity of proprioceptive stimulation, via tightness of a soft brace, might influence the effect of a soft brace [17, 46]. Hassan *et al.* [17] speculated that a non-tight brace provides more recurrent stimuli by allowing movement between the brace and the skin and thus elicits continuous response from cutaneous mechanical receptors. In contrast, a tight brace might provide constant pressure to which skin mechanoreceptors may adapt. We observed that a non-tight brace significantly reduced the amount of deviation in varus–valgus angles, while a tight brace did not. These reports suggest the potential role of the somatosensory system in the processing of proprioceptive input and highlight the importance of sensorimotor mechanisms in providing joint stability. There is a belief that regular use of a soft knee brace might cause weakness in the muscles surrounding the knee joint. However, Callaghan *et al.* [47] studied the potential negative effect of wearing a soft knee brace on knee muscles by measuring quadriceps maximum voluntary contraction and arthrogenous muscle inhibition. They showed that 6 weeks use of a soft knee brace did not have adverse effects on quadriceps maximum voluntary contraction and arthrogenous muscle inhibition, contradicting the belief that regular use of a soft knee brace causes muscle weakness.

Fig. 1 Frontal plane kinematics during level and perturbed walking

The mean (s.d.) of the knee varus–valgus angles during the stance phase of level and perturbed walking without the brace and with the brace for persons with **(A)** varus dynamic malalignment (varus is in the positive direction) and **(B)** valgus dynamic malalignment (valgus is in the negative direction).

Some limitations should be acknowledged. First, participants were informed about the occurrence of mechanical perturbations. Therefore they might have modified their walking pattern while anticipating perturbations. This was required for safety reasons but could have introduced bias due to an anticipation effect. Second, participants were subject to perturbations in four conditions over time. This could have led to bias due to a learning effect. Third, we acknowledge that skin markers create errors when estimating underlying bone kinematics during gait because of soft tissue artefacts [48]. However, this is a systematic error and alternative methods of assessing dynamic joint kinematics pose significant invasive risk to the participants (bone pins, radiation) [48, 49]. Moreover, repeated placement may cause variability in the placement of markers [48]. To reduce this source of variability, markers were placed by one examiner with several years of clinical experience and trained in identification of anatomical landmarks. Finally, the absence of the difference between a non-tight and a tight brace could be a consequence of inadequate power due to the small sample size of the study. Future studies with larger sample sizes are warranted to clarify whether tightness of a soft knee brace influences dynamic knee instability.

In conclusion, this study is the first to report that wearing a soft knee brace reduces objectively assessed dynamic knee instability in persons with knee OA. Wearing a soft brace results in an objective improvement of knee instability beyond subjectively reported improvement.

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