

Effects of a knee valgus unloader brace on medial femoral articular cartilage deformation following walking in varus-aligned individuals

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ABSTRACT

Background: Knee varus alignment may increase loading in the medial tibiofemoral compartment, which can increase strain on the articular cartilage. Knee valgus unloader braces seek to reduce loading through the medial femoral compartment, but their effects on cartilage characteristics during dynamic tasks have not been evaluated.

Objective: To determine the effects of a knee valgus unloader brace on medial femoral articular cartilage deformation following a single 5000-step walking protocol in individuals with varus-knee alignment.

Methods: Twenty-four healthy individuals (63% female, BMI = 22 ± 3 kg/m², age = 21 ± 3 years) completed two testing sessions (braced and unbraced) separated by one week. During both sessions, femoral cartilage ultrasound images were acquired prior to and following a 5000-step treadmill walking protocol at self-selected speed. Percent change scores in medial cartilage cross-sectional area (MCCA) were calculated and used as the primary outcome, and compared between the braced and unbraced conditions.

Results: There was no difference in percent change of MCCA between conditions (braced = -2.77% , unbraced = -3.15% , $p = 0.699$). Individuals whose cartilage deformed more than a previously established minimal detectable change ($MDC \geq 1.58$ mm²) deformed less during the braced condition (braced = -2.94% , unbraced = -6.34% , $p = 0.028$), compared to individuals who did not deform greater than the MDC ($n = 15$, braced = -2.67% , unbraced = -1.23% , $p = 0.210$).

Conclusions: There was no significant difference in MCCA percent change between the braced and unbraced conditions across the entire cohort; yet a valgus unloader braces may serve as a potential intervention strategy for reducing articular cartilage deformation in certain varus-aligned individuals who normally undergo measurable deformation during walking.

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1. Introduction

The amount of overall mechanical loading distributed through the medial tibiofemoral compartment during walking is approximately 2.5 times greater compared to the lateral tibiofemoral compartment [1]. Additionally, greater static knee varus alignment

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is hypothesized to further increase loading through the medial compartment during walking [2,3], which may increase articular cartilage strain. Excessive cartilage loading can elicit deleterious alterations in cartilage health, which may lead to eventual tissue breakdown [4–6]. Limiting cartilage loading in the medial tibiofemoral compartment may decrease the risk of idiopathic knee osteoarthritis development or posttraumatic osteoarthritis following joint injury.

Articular cartilage has viscoelastic elastic properties whereby its response to loading is dependent on the magnitude and rate of the load it is placed under [7,8]. Greater magnitude of loading, along with higher rates of loading, placed on the articular cartilage may lead to greater deformation of the, which can affect the long-term health of the joint and, subsequently, knee osteoarthritis risk [4,9]. Therefore, it is necessary to develop interventions aimed at regulating the mechanical loading placed on the articular cartilage of the knee in individuals who may be subject to excessive loading of the articular cartilage in the medial tibiofemoral compartment during walking. Knee valgus unloader braces have previously been demonstrated to reduce the peak knee adduction moment, a surrogate measure of medial compartment loading, during walking [10,11]. These braces operate via a three-point bending mechanism that applies valgus pressure to the joint line aimed at correcting varus knee alignment. Therefore, it is possible valgus unloader braces may serve as a clinically applicable method for reducing the load distributed through the medial tibiofemoral compartment and thereby lessen the strain on the articular cartilage.

Ultrasonography (US) is a valid and cost-effective tool for visualizing articular cartilage [12] and has previously demonstrated the capability to accurately and reliably assess articular cartilage deformation in the medial femoral compartment following normal walking [13,14], however US has never been used to measure the effect of valgus unloader braces on cartilage deformation following walking. Therefore, the purpose of this study was to determine if medial compartment femoral articular cartilage deformation differs following a single standardized walking protocol while wearing a valgus unloader brace compared to an unbraced condition in varus-aligned individuals. We hypothesized there would be less medial compartment cartilage deformation following the braced condition compared to the unbraced condition.

2. Methods

2.1. Design

We utilized a crossover design to assess medial femoral articular cartilage deformation across two conditions (i.e. braced and unbraced) separated by at least one week (9.13 ± 4.35 days). Participants were instructed to limit their physical activity on testing days to avoid excessive or abnormal lower extremity loading (i.e. lower extremity strength training), and to maintain normal levels of physical activity between testing sessions. The order of the walking conditions was counterbalanced using a Latin Square. Participants reported to the laboratory at the same time of day (± 2 h) for both sessions to limit the potential influence of diurnal variations [15]. Upon arrival, participants sat on a plinth in the long-sit position with the knees fully extended for 45 min to allow fluid rebound of the cartilage prior to imaging [16]. In the experimental condition, participants wore a valgus unloader brace on the dominant limb, defined as the limb an individual would prefer to use when kicking a ball [16]. US images of the medial femoral cartilage were obtained on the dominant limb prior to a 5000-step walking protocol and again immediately following the walking protocol.

2.2. Participants

We recruited a convenience sample of healthy individuals with $\geq 2^\circ$ of static knee varus [17] between the ages of 18 and 35 years. We excluded participants who reported any history of orthopedic lower extremity surgery or injury within the six months prior to participation, known or suspected pregnancy, or a body mass index (BMI) ≥ 30 . Preliminary analyses within our lab revealed a strong effect ($N = 2$, Cohen's $d = 1.87$) between the braced and unbraced conditions on cartilage cross-sectional area. Therefore, we conservatively estimated that we would need 24 participants in order to achieve a moderate effect ($d \gg 0.6$) between conditions for the current study with an alpha level of 0.05 and 80% power (G^*Power , v3.1.9.2) [18].

2.2.1. Screening protocol

Participants reported to an initial screening session during which knee alignment was determined using a long-lever goniometer [19]. For the assessment of baseline knee alignment, the participant stood with feet facing forward directly underneath corresponding acromion processes and weight evenly distributed between limbs. The superior lever arm was aligned to the ASIS and the knee joint center (defined as the center point between femoral epicondyles in the frontal plane). The inferior lever arm was aligned to the knee joint center and the ankle joint center (defined as the center point between the medial and lateral malleolus in the frontal plane). Mass(kg) and height (m) were measured and used to calculate BMI. Self-selected walking speed was assessed using two sets of infrared timing gates spaced one-meter apart (TF100, TracTronix). Starting approximately five steps before the first timing gate, participants were instructed to walk at a speed described as “comfortable walking over a sidewalk.” [20] Each participant completed 5 trials and the average walking speed was calculated and used for the treadmill walking protocol.

2.2.2. Ultrasonographic assessment of the femoral articular cartilage

While seated with their back against a wall, participants flexed their knee to 140° which was confirmed via a manual goniometer while keeping the limb in line with the torso. A measuring tape was secured to the length of the table so that the position of the posterior calcaneus could be recorded to allow for consistent positioning across trials [16]. A LOGIQe US system (General Electric Co., Boston, MA) with a 12 MHz linear probe was used to image the medial femoral articular cartilage. The probe was placed

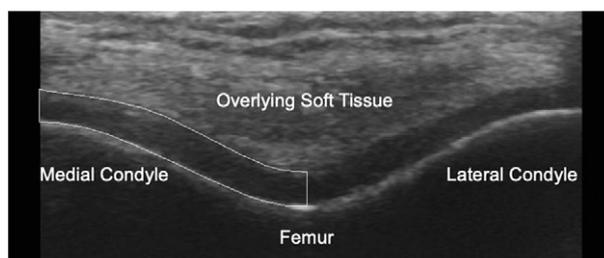


Figure 1. Ultrasonographic image of the femoral articular cartilage with the medial compartment cross-sectional area outlined.

transversely in line between the medial and lateral femoral condyles just superior to the patella and rotated in the sagittal plane to maximize sound reflection off the articular cartilage [21]. A transparent grid was placed over the US screen to improve reproducibility of the US image [16]. The midpoint of the intercondylar groove was aligned with the center of the grid. The level of the cartilage-bone interface at the edge of the image on either side was recorded in order to ensure consistent positioning of the probe across US assessments. Three images were collected from each knee at each time point. Strong intra-session reliability for assessing medial femoral articular cartilage deformation has been reported using this technique ($ICC_{2,k} = 0.966$) [16]. Following each loading condition, the participant was placed in the same position as the pre-loading US assessment using the tape measure, and US probe position was guided by the transparency grid on the US screen. Three images of the femoral articular cartilage were recorded from each knee. All post-walking images were captured within five minutes of the loading protocol. All US images were analyzed with the ImageJ software (National Institutes of Health, Bethesda, MD) by a single trained investigator who was blinded to condition (braced vs. unbraced) [22]. The femoral articular cartilage was divided into medial and lateral sections by identifying the midline at the most inferior point of the intercondylar groove [16]. Medial compartment articular cartilage area (MCCA) was segmented using a polygon function for each of the three images at each time point (pre- and post-walking) from which the area (mm^2) of the region of interest (ROI) was calculated (Figure 1). Percent change scores ($[(pre - post) / pre * 100]$) in cartilage area was calculated and averaged for statistical analysis.

2.2.3. Brace fitting protocol

Immediately following the pre-walking US assessments, participants were transferred from the plinth to a wheelchair in order to minimize knee loading not related to the walking condition. For the braced walking condition, a valgus unloader brace (Unloader One®, Össur Americas, Orange County, CA) was fitted by the same licensed certified athletic trainer per manufacturer instructions to the dominant limb while the participant was seated with knee flexed to approximately 80°. The brace was maximally adjusted to unload the medial compartment. Each participant took 30 steps to adjust to the brace and assess the fit of the brace on their knee. Adjustments were made as needed if the participant determined the fit was uncomfortable or if the brace was too loose. In order to account for the possible need of multiple adjustments, each participant completed four sets of 30 steps in total to standardize the number of steps completed (120 steps). The participant was transferred to and from the treadmill via wheelchair to control the amount of articular cartilage loading prior to the standardized walking protocol.

2.2.4. Unbraced condition

In order to account for the number of steps which occurred during the fitting of the braced condition, each participant took 120 steps in 30-step increments with a standardized rest time between increments prior to walking on the treadmill for the unbraced condition. The participant remained unbraced for the entire trial.

2.2.5. Treadmill walking protocol

Participants walked on a treadmill (4Front, WOODWAY, Waukesha, WI) at their self-selected speed for 5000 steps for each condition. Steps were visually counted for one minute, and the time necessary to complete 5000 steps was calculated (5000 steps/steps per minute). Participants continued walking on the treadmill at their self-selected speed for the time calculated. This protocol has previously been used to elicit femoral articular cartilage deformation [16].

2.3. Statistical analysis

2.3.1. Primary analysis

Means and standard deviations for all demographic data were collected for the entire cohort (Table 1). A Shapiro–Wilk test for normality was performed to confirm that data for each outcome measure were normally distributed. Additionally, stem and leaf plots were used to identify potential outliers for percent change in MCCA, which were defined as a point measured $\gg 3$ standard deviations from the mean. Inter-session intra-class correlation coefficients (ICC) were calculated to assess the reliability of baseline measures for articular cartilage area between days. ICC values were classified as weak ($\ll 0.5$), moderate (0.5–0.69), or strong (≥ 0.7) [23]. Two-tailed paired samples *t*-tests were used to compare percent change scores for the braced and unbraced conditions. The a priori alpha level was set to $P \leq 0.05$. All statistical analyses were performed using SPSS (v21.0; IBM Corporation).

Table 1
Participant demographics and outcome measures (mean \pm SD).

Participants	Entire cohort	Deformers	Non-deformers
	9 male, 15 female	3 male, 6 female	6 male, 9 female
Age	20.58 \pm 2.80	19.56 \pm 1.74	21.20 \pm 3.17
Height (m)	1.70 \pm 0.07	1.71 \pm 0.07	1.69 \pm 0.08
Mass (kg)	66.71 \pm 12.85	65.14 \pm 10.46	67.64 \pm 14.36
BMI	22.99 \pm 3.07	22.17 \pm 2.11	23.49 \pm 3.49
Knee varus ($^{\circ}$)	3.07 \pm 1.11	2.96 \pm 1.11	3.13 \pm 1.14
Walking speed (m/s)	1.35 \pm 0.17	1.34 \pm 0.12	1.35 \pm 0.19
Baseline Braced MCCA (mm ²)	45.98 \pm 5.08	43.68 \pm 4.82	47.36 \pm 4.87
Post-Braced Walking MCCA (mm ²)	44.73 \pm 5.49	42.43 \pm 5.25	46.12 \pm 5.32
Percent Change in Braced MCCA (%)	-2.77 \pm 3.46	-2.95 \pm 3.58	-2.67 \pm 3.51
Baseline Unbraced MCCA (mm ²)	45.81 \pm 5.11	44.12 \pm 5.49	46.82 \pm 4.77
Post-Unbraced Walking MCCA (mm ²)	44.42 \pm 5.65	41.35 \pm 5.50	46.27 \pm 5.05
Percent Change in Unbraced MCCA (%)	-3.14 \pm 2.96	-6.34 \pm 1.67	-1.23 \pm 1.51

MCCA: Medial Compartment Cross-sectional Area.

2.3.2. Post Hoc Analysis

A recent study by Harkey et al. [14] evaluating medial compartment articular cartilage deformation following walking calculated the minimal detectable change (MDC, ≥ 1.58 mm²) for MCCA to determine the amount of articular cartilage deformation that may be expected due to measurement error. Using this criterion, we stratified the original cohort into two groups based on the magnitude of change in MCCA observed during the unbraced walking condition. The first group, classified as deformers, was defined as individuals who demonstrated a change in MCCA ≥ 1.58 mm² during the unbraced walking condition. The second group, classified as non-deformers, was defined as those who demonstrated a change in MCCA deformation of $\ll 1.58$ mm² during the unbraced walking condition. Similar to the statistical analysis for the entire cohort, stem and leaf plots were used to identify potential outliers for percent change in MCCA, for each group, which were defined as a point measured $\gg 3$ standard deviations from the mean. Two-tailed paired sample *t*-tests were conducted to determine if there were differences between braced and unbraced conditions for the group of deformers and non-deformers, separately. We set alpha levels a priori for all comparisons at ≤ 0.05 . We did not correct for multiple comparisons as the post hoc tests were exploratory.

3. Results

Twenty-four of the total 82 healthy individuals who were screened for eligibility for the current study completed both the braced and unbraced sessions (62.5% female, 1.70 \pm 0.07 m, 66.71 \pm 12.85 kg, Table 1). Measures of baseline articular cartilage area for the medial condyle demonstrated strong reliability (ICC = 0.97, SEM = 0.37 mm²) between sessions. No outliers were detected within the entire cohort for percent change in MCCA. Additionally, no outliers were detected for the deformers and non-deformers groups once we stratified our cohort based on the previous MDC (1.58 mm²).

For the primary analyses, there were no significant differences between percent change for articular cartilage area for the medial condyle (braced = -2.77%, unbraced = -3.15%, $p = 0.699$, Figure 2) between braced and unbraced conditions. For the

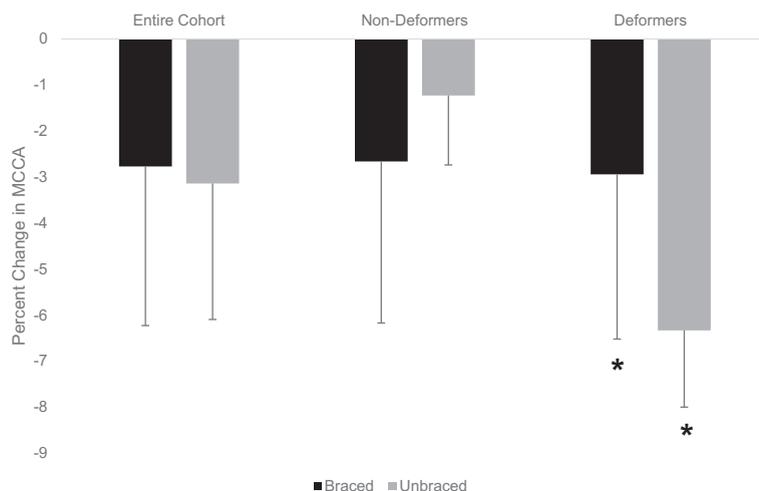


Figure 2. Bar graph representing the differences in percent change in medial compartment cross-sectional area between the braced and unbraced conditions for the entire cohort, as well as the deformer and non-deformer groups analyzed during the post hoc analysis. MCCA: Medial Compartment Cross-sectional Area, *indicates greater deformation ($P < 0.05$) in MCCA in the unbraced condition compared unbraced condition.

post-hoc analysis, deformers ($n = 9$) demonstrated less percent change for articular cartilage area during the braced condition compared to the unbraced condition for the medial condyle (braced = -2.94% , unbraced = -6.34% , $p = 0.028$, [Figure 2](#)). For the non-deformers ($n = 15$), we did not find any difference between articular cartilage area percent change for the medial condyle (braced = -2.67% , unbraced = -1.23% , $p = 0.210$, [Figure 2](#)) between braced and unbraced conditions.

4. Discussion

Contrary to our hypothesis, we did not find differences between the braced and unbraced conditions for articular cartilage deformation in the entire cohort. As part of an exploratory analysis, a subset of individuals ($n = 9$) who demonstrated medial femoral articular cartilage deformation greater than the MDC during unbraced walking demonstrated less deformation during the braced condition. Valgus unloader braces may have the capacity to resist articular cartilage deformation in varus-aligned individuals who normally demonstrate measurable femoral articular cartilage deformation during walking. Therefore, while valgus unloader brace may not influence articular cartilage deformation for all individuals, it is possible the valgus unloader brace can decrease medial tibiofemoral articular cartilage strain in individuals who experience strain through the medial femoral compartment during a 5000-step protocol.

Knee osteoarthritis (OA), a disease characterized by the breakdown of articular cartilage [24], is more prevalent in the medial tibiofemoral compartment compared to the lateral [25,26], which has been theorized to be due, in part, to the greater magnitudes of loading through the medial compartment [1]. Similarly, greater knee varus alignment may increase the mechanical loading of the medial femoral compartment during walking [2,3]. Therapeutic strategies aimed at reducing the mechanical load distributed through the medial compartment may be essential to maintaining long-term joint health. Valgus unloader braces have been shown to reduce knee adduction moment between 11 and 36%, a surrogate measure of medial compartment loading, during walking [10,11]. Similarly, while we did not evaluate measures of joint loading, the current study is the first to demonstrate a valgus unloader brace can reduce medial femoral articular cartilage deformation in a subset of individuals who undergo measureable deformation during walking. Together, the findings of previous studies [10,11] as well as the current study demonstrate that valgus unloader braces may effectively reduce medial compartment loading and articular cartilage deformation in a proportion of healthy varus aligned individuals who usually demonstrate deformation. These data assist in identifying individuals for whom a valgus unloader brace may be an effective intervention to decrease deleterious tissue changes in the medial tibiofemoral compartment.

Fifteen individuals (63%) in the current study did not demonstrate a measureable change in MCCA following walking [14]. It is possible that some of these individuals underwent femoral articular cartilage deformation in regions of the femoral articular cartilage that we were unable to measure with our US technique. The method for US image assessment in the current study captures, primarily, a portion of the anterior femoral articular cartilage [14]. Detecting articular cartilage deformation on posterior regions of the femoral condyle was not possible using the current technique. We did not assess walking biomechanics as part of the current study, and different knee biomechanics (e.g. knee flexion angle at heelstrike and knee flexion displacement) may contribute to loading of different regions on the articular surface [27]. Future studies may seek to characterize movement strategies in varus-aligned individuals before and after use of a knee brace.

While the ultrasound methods used in the current study are primarily for research purposes, ultrasound may be an inexpensive and clinically feasible method for assessing acute articular cartilage deformation following loading. To our knowledge, this is the first study to utilize ultrasound to measure articular cartilage deformation in conjunction with the use of a valgus unloader brace. The current study serves as the first step in determining the potential of the brace in eliciting tissue level changes. Further research using ultrasound to measure articular cartilage deformation following walking with the valgus unloader brace may increase confidence in the brace as being effective in modifying tissue deformation in a certain subset of individuals.

5. Limitations

While the findings of this study encourage further research into this area, there are several limitations to consider. First, we evaluated young, healthy participants with static varus alignment, no history of significant knee pathology or surgery, and with little variability in demographical outcomes such as height, weight, and age. Future studies should study participants who may be at-risk for, or previously diagnosed with, radiographic knee OA to determine the effectiveness of the valgus unloader brace in patient populations. Further, while we were sufficiently powered to evaluate the valgus unloader brace in our entire cohort, the stratification of the participants into deformers ($n = 9$) and non-deformers ($n = 15$) diminished the statistical power for the post-hoc analysis. However, these preliminary findings inform future research with larger sample sizes of deformers and non-deformers to attempt to distinguish the differences between these subgroups of individuals who may respond differently to valgus unloader braces. The current study examined how a valgus unloader brace may influence medial femoral cartilage deformation following a 5000 step walking protocol, however we did not assess walking biomechanics for the current study. Future research should examine the effects of a valgus unloader brace on medial femoral cartilage deformation, along with walking biomechanics, to better understand what biomechanical mechanisms may be responsible for the differences in cartilage deformation observed in this study. Another important consideration is that we were only able to assess a single section of the anterior femoral articular cartilage that was captured with US. It is possible that femoral articular cartilage deformation occurred in different regions of the femoral articular cartilage (i.e. central or posterior regions), which could not be visualized with the US method we utilized in the current study. Further, the ultrasound acquisition technique used in the current study was only able to detect changes to femoral articular cartilage and not tibial articular cartilage. We only captured US images immediately following the 5000-step intervention, and it is possible that individuals have varying responses to different amounts of loading. Additionally, while

we only evaluated the acute effects of a valgus unloader brace, future research is needed to evaluate the influence of multiple sessions on cartilage deformation.

6. Conclusions

Overall, there was no significant difference in MCCA percent change between the braced and unbraced conditions for the entire cohort. Lesser medial compartment femoral articular cartilage deformation was observed following the braced condition in individuals who demonstrated articular cartilage deformation exceeding the MDC during the unbraced walking condition.

Conflict of interest and source funding

The Unloader One® braces, used in the current study were supplied from Össur Americas, Orange County, CA.

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