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Bracing improves clinical outcomes but does not affect the medial knee joint space in osteoarthritic patients during gait

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Abstract

Purpose Osteoarthritis (OA) of the knee is commonly treated through the use of medial compartment unloading braces which have been shown to improve clinical symptoms. The objective of this study was to assess the effects of a medial compartment unloading brace on biomechanical measurements and clinical outcomes. We hypothesized that brace usage would lead to increased medial joint space and improved clinical outcomes.

Methods Ten patients with medial compartment OA were prescribed a medial compartment unloading brace and underwent dynamic biplane radiograph imaging while walking with and without the brace. The Western Ontario and McMaster University Osteoarthritis (WOMAC) Index was used to assess pain before brace wear and at the time of testing. The 3D position and orientation of the femur and tibia were determined using a model-based tracking technique.

Results Patients saw an average improvement of 33 % in their WOMAC scores ($p = 0.01$). This study failed to detect any statistically significant changes in the functional joint space, knee kinematics, or contact centre location between the braced and unbraced condition (n.s.).

Conclusion The data from this study, using a highly accurate (±0.6 mm and ±0.6°) 3D radiograph analysis of dynamic tibiofemoral motion, suggest that the brace is ineffective at increasing joint space. However, it was shown to be effective in improving clinical outcome and therefore should continue to be prescribed to patients even though the mechanism of its effectiveness remains unknown.

Level of evidence IV.

Keywords Kinematics · Osteoarthritis · Knee · Brace

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Introduction

Osteoarthritis (OA) is a very common source of pain and disability, leading to significant loss of function, decreased quality of life, and considerable medical expenses. Studies have estimated that over 27 million people in the United States are affected by OA, and 12 % of those are diagnosed with knee OA [6]. This leads to direct medical costs exceeding $321 billion annually [6]. Although the aetiology of OA is multifactorial and still not well understood, it is widely believed that mechanical loading of the joint plays an important role. For example, prior research has estimated that the medial compartment of the tibiofemoral joint in healthy subjects receives 62 % of the total joint load during the stance phase of gait, while the lateral compartment receives the remaining 38 % [5]. It has been hypothesized that this preferential loading of the medial compartment is why the medial compartment is more frequently affected by OA than the lateral compartment [18]. In patients with severe medial compartment OA, it has been suggested that the medial compartment may experience up to 100 % of the joint load due to joint alignment [18].

Various types of knee braces are often prescribed as a non-operative intervention for patients with knee OA. In an effort to lessen symptoms and possibly slow disease

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progression, some braces are designed to reduce forces in either the medial or lateral compartments. The premise of these braces is that increasing the joint space will unload the diseased compartment and improve patients' symptoms [13, 14]. Previous research has demonstrated that these braces do improve the symptoms associated with OA [9, 10, 15], but the extent to which these braces unload the medial compartment or increase the medial compartment joint space has shown mixed results. For example, previous research has shown that medial compartment unloading braces can in fact increase the medial joint space, but that this finding may not necessarily apply to all braces and may be limited to specific patient populations [13, 14]. The reason why these braces are not effective for all patients is not entirely clear, but it has been hypothesized that sub-optimal brace fixation in obese patients may limit the brace's efficacy [13]. Another potential explanation is that previous studies have relied on two-dimensional (2D) fluoroscopic-based measures of joint space which have excellent in-plane accuracy (particularly when compared to conventional video-based motion capture systems) but limited out-of-plane accuracy [3]. Consequently, relying on 2D measurement techniques may limit the accuracy with which changes in the medial compartment joint space due to brace usage can be assessed.

Therefore, the objective of this study was to use a highly accurate, dynamic, 3D in vivo technique to assess the effects of a medial compartment unloading brace on the following: (1) the functional joint space of the medial and lateral compartments, (2) estimated joint contact locations, (3) conventional tibiofemoral joint kinematics, and (4) clinical outcome. It was hypothesized that knee brace use would be associated with increased medial compartment joint space and improved clinical outcome.

Materials and methods

After Institutional Review Board approval (IRB #5415) and informed consent were obtained, ten patients (9 men, 1 woman; mean age 59.5 ± 7.3; range 48–70) were enrolled in the study. Patients had a history of OA predominantly in the medial compartment and were diagnosed with medial compartment narrowing through the use of standing anterior/posterior radiographs. All patients had previously tried other treatment options including NSAIDS and physical therapy. Patients were excluded from the study if they had ligament damage in their affected knee or any prior surgical procedure performed on their affected knee. All patients were prescribed a medial compartment unloading brace (OA Adjuster, DonJoy, Vista CA) and allowed a 2-week adaptation period prior to testing. Patients were required to wear the brace while ambulating for a minimum of 3 h per day.

Testing procedures

Patients were positioned on a standard treadmill, (Nordic Track A2550, ICON Health and Fitness, Logan, UT) with their right knee centred within the 3D imaging volume of a biplane radiograph system. Dynamic biplane radiograph images of the knee were collected at 120 frames/s during treadmill walking at 2.3 mph and while standing [1]. Testing began by acquiring a static standing trial to ensure that the femur and tibia were both centred in the 3D imaging volume. After the initial standing trial, three walking trials were performed with images acquired for 2 s. The trials were started just prior to heel strike and continued through the entire stance phase of the gait cycle. Subjects were first tested without the knee brace to allow them to become familiar with the testing protocol. Upon completion of the non-braced trials, a custom radiograph translucent knee brace provided by the manufacturer (OA Adjuster, DonJoy, Vista CA) was fit to the patient by a trained orthotist. This brace was identical to the patients' standard brace, with the exception of the rigid vertical supports being replaced with a radiolucent metal alloy with stiffness similar to the metal used in the standard brace. The testing protocol was then repeated with patients wearing the custom medial compartment unloading brace.

Following completion of testing, a computed tomography (CT) scan of the distal femur and proximal tibia was acquired for each patient. CT scans were performed with a clinical scanner (GE Healthcare Lightspeed 16, Buckinghamshire, United Kingdom), using a slice thickness of 0.6 mm and slice spacing of 0 mm between successive slices in the axial plane. The CT images had a 28-cm field of view and 512 × 512 pixel image size, corresponding to an in-plane resolution of 0.55 mm/pixel. 3D volumetric bone models (Fig. 1) were created from the CT scan by isolating the femur and tibia from surrounding bones and soft tissues using commercial software (Mimics 13.1, Materialise, Ann Arbor, Michigan).

The primary tool used to assess the clinical effect that the use of a medial compartment unloading brace had on patients' pain and function was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). This subjective outcome measure has been shown to reliably indicate the patient's pain levels and function [8]. Total WOMAC scores are reported on a scale of 0–100, with a score of 100 indicating the highest function and least pain. The pain subset scores are reported on a scale of 0–28, with a score of 28 representing no pain. The function subset scores are reported on a scale of 0–68, with 68 representing full function. These subjective clinical data

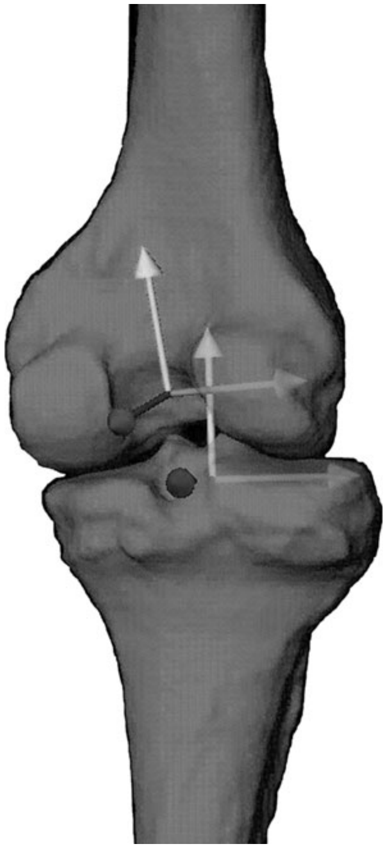

Fig. 1 Bony landmarks on the patient-specific three-dimensional models were used to create the anatomical coordinate systems of the femur and tibia. These coordinate systems were paired with the information from the model-based tracking technique to calculate the three-dimensional kinematics

were acquired at two time points: before subjects began wearing the brace and after completing the 2-week adaptation period.

Measuring tibiofemoral joint motion

The 3D position and orientation of the femur and tibia were determined for each frame of the biplane radiograph images using a CT model-based tracking technique (accuracy ±0.6 mm and ±0.6°) [1]. The model-based tracking technique creates a pair of digitally reconstructed radiographs (DRRs) from the CT bone model, and then optimizes the correlation between the DRRs and the biplane radiograph images. In order to express joint motions in anatomically relevant directions, subject-specific anatomical coordinate systems were defined for both the femur and tibia with the use of custom software as previously described in detail (based on Open Inventor 5.0, Mercury Computer Systems, Chelmsford, MA) [19]. The origin of the femoral coordinate system was centred at the midpoint of the medial and lateral condyles of the femur. Similarly, the origin of the tibial coordinate system was centred halfway between the most medial and most lateral aspects of the tibial plateau.

Using custom software, the functional joint space was determined for each trial. This was accomplished by calculating the minimum 3D distance between the femur and the tibia bone surfaces in both the medial and lateral compartments for each frame of data. These minimum distances were then averaged across all frames of each trial from heel strike to toe-off. For each compartment, this average minimum distance between the femur and tibia was defined as the functional joint space. In addition, an estimate of the joint contact centre location was determined for each frame and expressed relative to the tibia coordinate system as previously described [2, 4]. Using these data, the average contact centre in the medial/lateral and anterior/posterior direction was calculated for both the medial and lateral compartments. Similarly, the contact centre range in the medial/lateral and anterior/posterior directions was calculated for each compartment. These outcome measures (functional joint space, average M/L contact centre, average A/P contact centre, M/L contact centre range, A/P contact centre range) were averaged across all trials and subjects for the braced and unbraced conditions.

The 3D motions of the tibia relative to the femur were also determined from the model-based tracking data. The conventional kinematics, i.e. the rotations and translations of the tibia relative to the femur, were defined with respect to the anatomical coordinate systems created for each bone. The rotations were calculated in order of flexion/extension, abduction/adduction, and internal/external rotation. The anterior/posterior and medial/lateral translations of the tibial origin relative to the femoral origin were also calculated [20]. The ranges of these conventional kinematic outcome measures (3 rotations, 2 translations) were calculated for each trial.

Statistical analysis

The sample size was determined based on previous research reporting an average increase in joint space of 1.2 ± 1.3 mm. Based on these data, 10 patients provided 80 % power to detect a change in functional joint space of 1.0 mm ($\alpha = 0.05$, $\beta = 0.20$) when using a one-sided paired t test [7, 13, 14]. Paired t tests were used to compare the effects of brace conditions (i.e. braced versus unbraced) on the functional joint space, contact centres, contact centre range, and rotations and translations of the tibia relative to the femur. WOMAC scores (pre-brace versus post-brace) were also analysed via paired t tests. Statistically significant differences were set at $p < 0.05$.

Results

Clinical outcome

There was a statistically significant improvement in the patients' subjective assessment of pain and function, denoting a positive clinical effect ($p = 0.01$). Specifically, total WOMAC scores improved an average of 33 ± 39 % from pre-brace usage (60.3 ± 23.6; range 30.8–88.5) to post-brace usage (75.5 ± 17.2; range 43.5–93.3, $p = 0.01$). The WOMAC pain scores subset improved an average of 41.3 ± 42.5 % from pre-brace usage (17.2 ± 6.3; range 9–24) to post-brace usage (22.5 ± 3.4; range 18–26; $p = 0.01$). The function portion of the WOMAC scores improved an average of 33.0 ± 43.9 % from pre-brace usage (40.7 ± 16.8; range 19–62) to post-brace usage (50.9 ± 13.3; range 24–64; $p = 0.01$). A statistically significant change was not found in the stiffness category (n.s.).

Functional joint space

In the walking trials, the functional joint space in the medial compartment was almost identical in the braced (0.7 ± 0.5 mm; range 0.3–1.8 mm) and unbraced (0.7 ± 0.6 mm; range 0.4–1.8 mm) conditions (n.s., Fig. 2). For the lateral compartment, no statistically significant differences were detected in the functional joint space between the braced condition (3.7 ± 1.0 mm; range 2.6–6.1 mm) and the unbraced (3.6 ± 1.1 mm; range 2.7–6.3 mm) condition (n.s., Fig. 2).

Estimated joint contact centres

The location of the average joint contact centre was not found to be statistically significantly different between the braced and unbraced conditions (n.s., Fig. 3). In the joint's medial compartment, the average joint contact centre was located 30.3 ± 4.9 mm medial and 2.5 ± 7.7 mm anteriorly to the origin of the tibia coordinate system in the unbraced condition. For the braced condition, the average joint contact centre was located 30.4 ± 4.9 mm medial (n.s.) and 2.8 mm ± 6.9 mm anterior (n.s.) to the origin of the tibia coordinate system. In the joint's lateral compartment, the average joint contact centre was located 18.8 ± 3.2 mm lateral and 0.9 ± 6.2 mm anterior to the origin of the tibia coordinate system in the unbraced condition. For the braced condition, the average joint contact centre was located 18.9 ± 3.1 mm lateral (n.s.) and 0.6 ± 6.1 mm anterior (n.s.) to the origin of the tibia coordinate system.

The contact centre ranges were also not found to be different between the braced and unbraced conditions (n.s., Fig. 4). In the joint's medial compartment, the medial/lateral (4.1 ± 3.2 mm) and anterior/posterior (10.0 ± 3.3 mm) contact centre ranges during the braced condition were not significantly different than the medial/lateral (4.4 ± 3.1 mm, n.s.) and anterior/posterior (9.6 ± 3.5 mm, n.s.) contact centre ranges during the unbraced condition. In the joint's lateral compartment, the medial/lateral (3.3 ± 2.5 mm) and anterior/posterior (7.0 ± 3.2 mm) contact centre ranges during the braced condition were not significantly different than the medial/lateral (3.0 ± 2.3 mm, n.s.) and anterior/posterior (7.7 ± 3.8 mm n.s.) contact centre ranges during the unbraced condition.

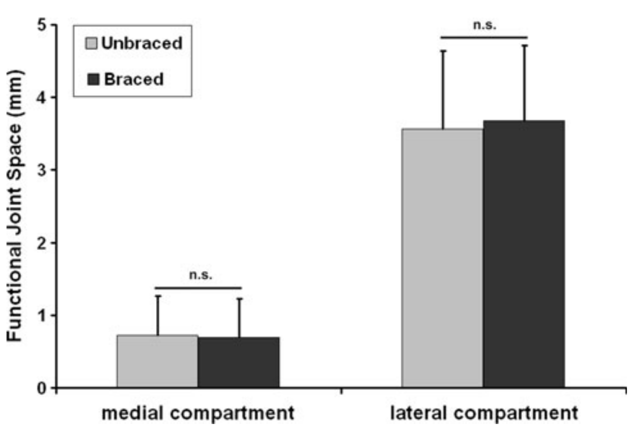

Fig. 2 The study failed to detect any statistically significant difference in functional joint space of the medial or lateral compartments during walking (n.s.)

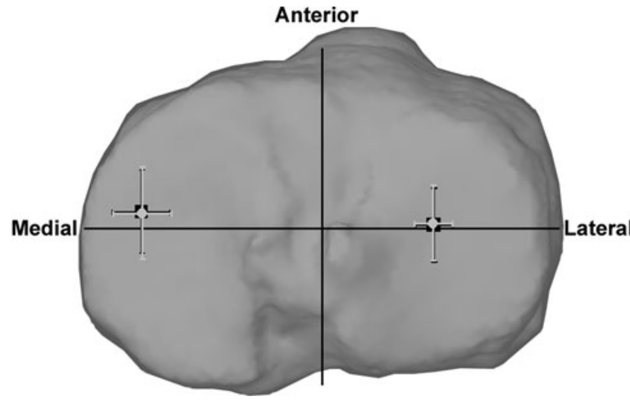

Fig. 3 There was no statistically significant difference in the average joint contact centre location between the braced (*squared*) and unbraced (*circled*) conditions in either the medial (n.s.) or lateral (n.s.) compartments. Data are reported as mean ± standard deviation and shown on the tibial plateau

Tibiofemoral joint kinematics

No statistically significant differences were detected in any of the joint rotations during walking trials with the use of the brace (n.s.). Specifically, the flexion/extension was

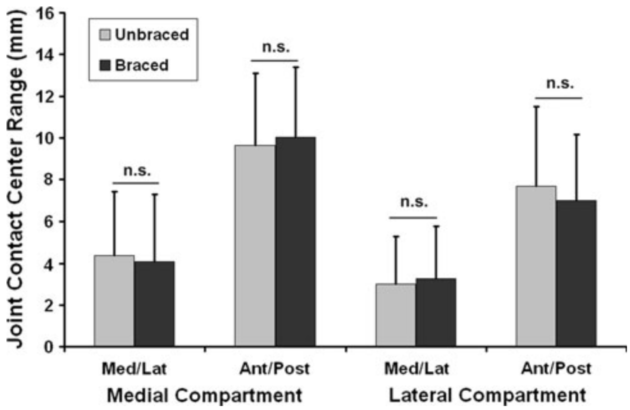

Fig. 4 No statistically significant differences in the joint contact centre ranges were detected between the braced and unbraced conditions

1.2° ± 4.8° in the unbraced condition and 10.3° ± 4.4° in the braced condition (n.s.), internal/external rotation was 6.9° ± 2.0° (unbraced) and 6.5° ± 3.0° (braced, n.s.), and the abduction/adduction was 2.8° ± 1.1° (unbraced) and 2.6° ± 0.8° (braced, n.s.). No statistically significant differences were detected in the range of joint translations associated with brace usage as well (n.s.). Specifically, the medial/lateral translation was 2.1 ± 0.7 mm in the unbraced condition and 2.1 ± 0.6 mm in the braced condition (n.s.), while the anterior/posterior translation was 6.8 ± 3.3 mm (unbraced) and 5.4 ± 2.0 mm (braced, n.s.).

Discussion

The most important finding of the present study was that the use of a medial compartment unloading brace did not result in significant changes in either the medial or lateral compartment joint space. However, use of the brace still resulted in improved clinical symptoms in patients with medial compartment OA. Previous studies have documented very subtle changes in the medial compartment joint space—typically in the range of 0–1.3 mm—that occur with brace usage [7, 13, 14]. Although the results reported in this study are certainly at the low end of this range, it is important to recognize that these previously reported studies measured medial condyle separation at specific points in the gait cycle (i.e. heel strike, midstance, toe-off). In contrast, the current study calculated the functional joint space as the average minimum distance between the femur and tibia over the entire stance phase. It is possible that the efficacy of the brace tested in this study varies throughout the stance phase, and consequently our technique for calculating the functional joint space may not appropriately represent the maximum efficacy of the brace. In addition, it is likely that discrepancies between this study and previously published studies are also influenced by the patient populations, testing protocols, differences between 2D versus 3D imaging techniques, and/or the segmentation of data into the various portions of the gait cycle.

The clinical improvements reported in this study are consistent with previous studies that have examined the effects of knee braces on patients with OA [11–13, 16, 17]. For example, the 33 % improvement in the WOMAC score is consistent with the study by Pollo and colleagues who reported that an unloading knee brace resulted in a 36 % increase in the patient's WOMAC score [16]. Similarly, Kirkley and colleagues reported a 20–30 % improvement in the WOMAC score over 3–6 months of brace usage [12]. Other studies have also reported statistically significant improvements in clinical outcome as a result of brace usage, using outcome measures such as the visual analogue pain score or Hospital for Special Surgery Score [11, 17].

Although the underlying premise of medial compartment unloading braces is that they decrease pain and improve function by increasing the medial compartment joint space, this study failed to detect an increase in the functional joint space of the medial compartment due to brace usage. In addition, the study also failed to detect statistically significant differences in any of the other measures of joint motion (i.e. tibiofemoral joint kinematics, average joint contact centres, or joint contact centre ranges). These findings tend to suggest that changes in tibiofemoral joint motion due to brace usage are not the most likely mechanism responsible for the improvements in clinical symptoms (i.e. higher WOMAC scores). Alternatively, it is possible that brace usage changes joint motion or joint alignment in a manner that reduces medial compartment loads, but that these changes are very subtle and within the uncertainty of the measurement technique.

There were several limitations associated with this study. The very small sample size ($n = 10$) is a limitation of this study and, as such, it is possible that much of the data may be subjected to a type II error. Patient compliance for wearing the knee brace was not monitored, but all patients reported wearing the brace for at least the recommended time of 3 h per day. Another potential limitation of the study is that the order of testing (unbraced, braced) was not randomized. This was done to familiarize the patients with the testing procedure. Another limitation of the study was the identification of heel strike and toe-off. The foot was not in the biplane radiograph system's imaging volume, and consequently, motion of the tibia was used to estimate heel strike and toe-off. Another potential limitation of this study is that the 2–3-week adaptation period may have been insufficient to alter patients' joint mechanics. Richards et al. [17] allowed for an adaptation period of 6 months before testing patients in the brace. Studies by Komistek et al. and Naduad et al. [13, 14] did not utilize any adaptation period before testing patients and also showed mixed results. It is possible that a different adaptation period is necessary for joint loading patterns to change significantly, allowing patients to show increased kinematic changes or report further changes in their pain and function. Also, instead of setting the brace to a uniform valgus angle, each patient had the brace set to and angle that was tolerable.

Conclusion

While the specific mechanism responsible for providing this relief in clinical symptoms is not yet understood, it is unlikely that the mechanism is related to changes in joint motion during walking. However, use of the brace does lead to improved patient subjective outcomes and provides a low cost, non-invasive clinical intervention that can be used in the management of OA. Therefore, the medial compartment unloading brace should continue to be prescribed to patients seeking a non-surgical treatment option.

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