EFFECT OF KNEE VALGUS UNLOADER BRACE IN VARUS- ALIGNED INDIVIDUALS ON FEMORAL ARTICULAR CARTILAGE DEFORMATION ACUTELY FOLLOWING WALKING PROTOCOL

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ABSTRACT

Joshua Alton Valentine: Effect of knee valgus unloader brace in varus-aligned individuals on femoral articular cartilage deformation acutely following walking protocol
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Progression of knee osteoarthritis (OA) has been associated with excessive cartilage loading. Varus knee malalignment has been hypothesized to increase the load through the medial compartment of the knee. The purpose of our study was to examine the effects of a valgus unloader knee brace in individuals with varus knee alignment on medial femoral articular cartilage deformation following a standardized walking protocol.

Medial compartment cartilage area (MCCA) was measured in 24 healthy subjects pre and post walking 5000 steps across two conditions: braced and unbraced. Percent area change was measured from pre to post in each condition and evaluated via paired samples t-test.

There was no difference in percent change of MCCA between conditions. A post hoc analysis found a subgroup of individuals, who deformed more than the minimal detectable change for cartilage area, deformed less during the braced compared to the unbraced condition. These findings suggest a valgus unloader knee brace may decrease the mechanical load on the medial femoral articular cartilage in varus individuals who experience measureable deformation during usual unbraced walking.

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CHAPTER 1

It is estimated that 14 million Americans suffer from symptomatic knee osteoarthritis (OA).[1] The disease is characterized by a chronic and abnormal remodeling of joint tissues including degradation of the cartilage, osteophyte formation, and subchondral bone thickening[2]. Activities of daily living become increasingly difficult as the pain and stiffness associated with knee OA worsen[3], and in severe cases can lead to surgical joint replacement.[4]

Progression of knee OA is often associated with abnormal biomechanics and tibiofemoral malalignment.[4-5] Greater knee varus angle is hypothesized to increase the load through the medial compartment of the knee[6-7], which may also increase the stress on the articular cartilage of the medial femoral condyle. Articular cartilage is viscoelastic and deformation of the tissue occurs normally during weight-bearing activities.[8] However, excessive loading of the cartilage may predispose an individual to articular joint pathology. Historically, the load through the medial compartment of the knee has been measured via the knee adduction moment (KAM).[9] This moment quantifies the effect of the ground reaction force vector as it passes medially to the knee joint center, and serves as a surrogate measure of medial knee compartment loading while walking.[10] An increased KAM has been correlated to the onset of knee OA.[9] In patients already suffering from knee OA, an increased KAM through the medial compartment hastens the progression of the disease and increases pain while weight-bearing.[4]

Valgus unloader braces have been used as an intervention to treat individuals with medial knee OA.[11,27-30] They operate via a three-point bending mechanism that applies valgus pressure to the joint line to correct varus knee alignment. In patients suffering from knee OA, these braces have demonstrated reductions in pain and improvements in daily function.[11] Valgus unloader braces have also been shown to reduce the KAM by up to 30%.[12] However, further research is needed to determine the effectiveness of these orthoses at reducing the amount of femoral articular cartilage deformation during self-selected walking.

Late-onset osteoarthritic changes, including joint space narrowing and osteophyte presentation, have been traditionally identified by radiography.[13] However, radiography is limited by its inability to identify early cartilage erosion and thickness changes. Ultrasonography (US) is becoming more frequently used as a mode of identifying femoral cartilage changes.[13] US is a reliable alternative when compared with magnetic resonance imaging (MRI), the current standard for the evaluation of knee cartilage thickness.[13-14] US is also sensitive to acute femoral cartilage changes following self-selected walking.[15] Therefore, the purpose of this study was to determine the effect of a valgus unloader brace condition on the acute change in medial femoral condyle cartilage thickness following a standardized walking protocol as captured by ultrasonography.

Specific Aims

Specific Aim: To determine if medial compartment femoral articular cartilage deformation differs following a standardized walking protocol (5000 steps at self-selected walking speed) when healthy participants wear a valgus unloader brace compared to an unbraced condition

Hypothesis: There will be greater medial compartment femoral articular cartilage deformation following the unbraced condition compared to the braced condition

CHAPTER 2

The knee, comprised of the tibiofemoral and patellofemoral joints, plays a pivotal role in daily function and ambulance. Articular cartilage lines the surface of both the tibial and femoral condyles. A meniscal cartilage also protects the medial and lateral tibial plateaus. These structures, in addition to muscles, ligaments, and bony congruity provide stability at the knee. Injury or disease to these structures can often be debilitating. The knee joint transmits a significant amount of weight-bearing load during gait. In particular, the medial compartment of the knee in neutrally aligned limbs has been demonstrated to absorb 60-70% of that load[5]. This repetitive stress can result in deterioration of the cartilage that lines the tibial plateau and femoral condyles. That deterioration often leads to knee osteoarthritis (OA), a degenerative condition of the articular surface of the knee[16]. Osteoarthritis primarily affects weight-bearing joints and is especially prevalent at the knee due to the repetitive loading of the joint during gait and most activity[4]. Thus, it is important to explore pathological mechanics that predispose an individual to progressive knee OA in addition to possible interventions to prevent and alleviate symptoms of knee OA.

Properties of Cartilage

Cartilage has several viscoelastic properties that allow it to serve as an effective distributor of compressive forces. The two phases that compose cartilage include a fluid phase (60-80%) composed of water and electrolytes and a solid phase (20-40%) composed of collagen and various protein types[17]. These phases work in conjunction to displace compressive loads and reduce the overall stress placed on the joint. Cartilage composition is monitored by chondrocytes within the tissue that, when activated, produce inflammatory response proteins[18]. These proteins include both degrading and remodeling enzymes that work to allow healthy cartilage deformation and reformation in response to compressive stress placed on the tissue[18]. Acute cartilage deformation has been also shown to occur following walking and running in healthy subjects[15]. Harkey et al. were able to demonstrate a 6.7% decrease in medial femoral cartilage thickness following approximately thirty minutes of walking[15]. In the control condition (thirty minutes of sitting), Harkey et al. were also able to demonstrate a 3.4% increase in cartilage thickness[15]. This can be attributed to the natural reformation of cartilage when not weight-bearing.

Etiology and Progression of Knee OA

OA is a complex disease that encompasses the entire joint as a whole including the cartilage, subchondral bone, and synovium. OA is characterized by persistent inflammation of the joint originally thought to be caused by mechanical overloading of the joint[18]. However, the etiology behind OA may be more complex. The pathophysiology of the disease progresses due to an unbalancing of the enzymes released by the chondrocytes within the cartilage[18]. This causes a reflexive stiffening of the cartilage over time characterized by calcifications that form along the chondral-bone interface. The cartilage no longer deforms effectively, resulting in a less effective distribution of load across the joint[18]. The result of this is the formation of chondral lesions, osteophyte development and synovitis[18].

Researchers have examined several predisposing factors to the development of knee OA. History of knee injury in an individual has been shown to significantly increase the risk for the development of knee OA[19]. Posttraumatic knee OA has been shown to occur in 30% of the population within 5 years of ACL injury[20]. Age can also predispose an individual to knee OA, with 12.1% of the population aged 60 and older affected by this disease[3]. Changes in femorotibial (FT) cartilage thickness over time appear to indicate that those individuals are susceptible to OA progression. Eckstein et al. were able to correlate decreases in articular cartilage thickness with progressive pain levels[21]. They go on to suggest cartilage thickness changes are a strong marker for progressive OA and may be used as an outcome measure in future studies[22]. Indeed, in a previous study, Eckstein et al. were able to identify mean changes of 30% in the articular cartilage on measures performed *in vitro* with a load of 150% bodyweight[8]. Knee malalignment has been identified as a risk factor for developing OA[4,7,16]. Malalignment mechanically increases the compressive load in either compartment of the knee. Increased load can result in degenerative changes in the articular cartilage, a precursor for knee OA. Various structural factors in the knee can contribute to malalignment including the meniscus, ligaments, and subchondral bone[6]. Brouwer et al. identified normal alignment at the knee as between 182 and 184 degrees measured using the FT angle on an AP radiograph while weight-bearing[16]. FT angle has also been measured clinically by identifying the midpoint between the ASIS and the greater trochanter then drawing an axis line to the knee joint center. Another axis line is drawn from the knee joint center to the ankle joint center, and the resultant angle is a measure of the FT alignment[22]. In a study that compared knee malalignment to the progression of OA, there is positive correlation between varus malalignment and increased risk of medial compartment OA. There is also positive correlation between valgus malalignment and the development of lateral compartment OA[7]. In addition, patient-reported pain severity is associated with malalignment and shown to increase as knee malalignment increases[7].

Knee Adduction Moment

An effective method for measuring load placed on the medial compartments of the knee is the measurement of the knee adduction moment (KAM). This moment is a measure of the ground reaction force along the lever arm that runs medial to the knee during midstance in the gait cycle[10]. KAM is a major determinant of the medial to lateral load distribution across the knee joint[16]. Improper distribution of that load is what influences degenerative changes in the cartilage. Varus malalignment greatly influences KAM. Knee varus has been shown to increase the medial moment arm and load on lateral compartment, while knee valgus has been shown to increase lateral moment arm and load on lateral compartment[6]. A study that utilized knee implants to measure TF contact forces showed a correlation between the KAM and the medial contact force at the knee[10]. KAM and medial contact forces reached peak levels at both the early and late phases of midstance but were significantly correlated during the early phase[10]. This same study discovered that a reduction in KAM by 200% reduced the medial contact force by 100%[10]. This supports the theory that reducing the KAM directly reduces the load placed unilaterally through the medial compartment at the knee. It can be inferred that interventions designed to reduce KAM may ultimately diminish the forces being transmitted through the knee joint.

Justification for Ultrasonography

Historically, radiographic imaging has been used to identify cartilage degeneration. The Kellgren/Lawrence grading scale was formulated as a means of objectively determining the progression of OA[23]. A higher grade correlates to a greater number of osteophytes identified on the radiograph in the free joint space[25]. The captured image is then graded on the Kellgren/Lawrence scale by trained clinicians to identify the severity of the degeneration[6-7,16].

However, the K/L scale serves as a primarily retrospective diagnostic tool. Radiographs are limited in that they only display bone or osteophytic structures. There are many morphological changes that occur to the articular cartilage before the osteoarthritic process truly commences. Magnetic resonance imaging (MRI) has commonly been used to identify connective tissue structures and cartilage[24]. It is able to offer an image of the entire joint, identifying morphological changes not apparent on radiography. However, MRI has been shown to not be cost-effective[24]. Further, MRI has several limitations when it comes to identifying acute cartilage changes[8], including inability to effectively load the joint while being imaged and the length of time an individual needs to be still post-activity if changes were measured following a loading protocol. The process of taking an MRI is also not time-efficient. Boocock et al. used MRI to capture cartilage thickness changes following a running protocol, with a major limitation being that the process of taking the MRI took between 10 and 13 minutes on average[25]. TF cartilage specifically is difficult to measure due to the relative thinness of the articular cartilage resulting in higher precision errors[21]. Even 10 minutes of non weight-bearing can allow reformation of the cartilage and alter results. There is evidence to support that diagnostic ultrasound (US) is an effective measure at the knee to determine cartilage thickness and clarity as verified by traditional MRI or knee arthroscopy[13-14,26]. US is also sensitive to subtle changes in cartilage thickness before and after activity[15].

To obtain an image of the anterior articular cartilage lining the femoral condyles and trochlea, the best practice with US is to have the patient in a seated, supine position with one knee maximally flexed and the back flush against the wall[15,26]. The transducer head is then placed just proximal to the superior patella and perpendicular to the length of the extremity, with the depth and focal zone optimized to capture the cartilage[26]. Transparent grids placed over the screen have been shown to be an effective strategy to maintain consistent image positioning across trials to limit user error[15].

Unloader Brace Design and Effect

The unloader brace is a knee orthosis that operates via a three-point bend system. In valgus unloader braces specifically, these three points apply pressure at strategic positions at, above, and below the knee joint to correct exaggerated varus frontal plane alignment[27]. One point of pressure is along the lateral joint line and the other two are located medially both proximally and distally to the joint line. The point along the lateral joint line has the capacity to be tightened by a screw to increase pressure along the lateral joint. This increases the valgus compressive force, therefore decreasing the varus angle at the knee. In surrogate models fitted with this brace, there was an average varus angle decrease of 7 degrees[27]. Dessery et al. compared three different types of braces including a functional knee brace (ACL brace), valgus brace with three-point bending mechanism (V3P brace), and an unloader brace that operated by creating valgus and external rotation tension at the knee (VER brace)[38]. When tested in a sample of individuals with symptomatic medial compartment OA, all three braces relieved pain over a several months period, with the only difference being that the KAM impulse was decreased in the VER brace group[38]. Off-the-shelf unloader braces are capable of between 0-4 degrees of valgus adjustment[12,29]. The instrument to be used in this current study is a valgus unloader brace that operates via a three-point bending mechanism. There is research to suggest custom braces are more effective at decreasing varus alignment and decreasing KAM[30], but it has not been shown to be statistically significant and is neither cost or time effective.

Fantini Pagani et al. looked at the impact of a valgus unloader brace on KAM[29]. In a study of 15 healthy males of similar body composition, they found that the greatest change in knee adduction moment during walking was under the brace condition that reduced varus alignment by 8 degrees, resulting in KAM decreased by 36% compared to a control trial with no orthosis[29]. Similarly, a second study was able to demonstrate a 20-30% decrease in KAM when a valgus unloader brace was used as an intervention in a group of young, healthy individuals[12]. It can be inferred that because an unloader brace greatly decreases the KAM and medial load, it can also decrease the overall acute change in femoral cartilage thickness.

Table 1. Review of valgus unloader brace effects on KAM

Study	Sample size	Sample characteristics	Intervention	Brace condition	KAM reduction
Draganich et al.	10	Symptomatic varus gonarthrosis age 50.8+/-5.4	Custom + off-the-shelf valgus unloader brace	Patient-determined	15%
Fantini Pagani et al.	16 male	Healthy age 26.7+/-3.9	Off-the-shelf valgus unloader brace	Neutral, 4°, 8°	11-36%
Lindenfield et al.	11	Symptomatic varus gonarthrosis	Valgus unloader brace	Unspecified	10%
Orishimo et al., 2013	12 (9 male, 3 female)	Healthy age 32+/-10	Valgus unloader brace	1/2 tension, max tension	25-30%
Pollo et al.	11 (10 male, 1 female)	Symptomatic varus gonarthrosis age 53.2+/-9.8	Custom valgus unloader brace	4° varus	13-20%

Conclusion

As of yet, no study has looked at the use of an unloader brace as an intervention with cartilage thickness changes as an outcome measure. Force load through the medial compartment has been historically measured as the KAM. However, identifying changes in cartilage thickness is a more direct measure of the potential degenerative changes at the knee joint. Therefore, if an unloader brace is truly effective at diminishing cartilage thickness changes during activity, there is further support for its use as an intervention in individuals at risk for developing knee OA.

CHAPTER 3

Design

We utilized a crossover design and medial femoral articular cartilage area was measured across two conditions (i.e. braced and unbraced) at two time points (i.e. pre and immediately post-walking). Walking conditions were separated by at least one week. Participants were instructed to limit their physical activity on testing days to avoid excessive or abnormal cartilage loading. Participants were also instructed to maintain their normal level of physical activity between testing sessions. The order of the walking conditions was counterbalanced. In the experimental condition, the subject wore an unloader brace on the dominant limb, defined as the limb an individual would prefer to use to kick a ball. US images were obtained on the dominant limb. A single trained investigator completed all analyses. The investigator was blinded to condition (braced vs unbraced) but was aware of the sequence of which each image was collected for image post-processing.[33]

Participants

A convenience sample of healthy individuals between the ages of 18 and 35 was recruited. We found a strong effect (N=2, Cohen's $d = 1.87$) between conditions for decreased cartilage thickness in a preliminary study. With an alpha level of 0.05, we calculated that we would need 24 participants to achieve a moderate effect ($d > 0.6$). We excluded participants who reported any history of orthopedic lower extremity surgery or injury within the 6 months prior to participation, known or suspected pregnancy, or a body mass index (BMI) ≥ 30. Participants were excluded if they did not meet the minimum requirements for varus knee alignment (≥ 2°) established at an initial screening session.

Data Collection Procedures

Screening Protocol

Participants reported to an initial screening session during which knee alignment was determined using a long-lever goniometer[22,31]. For the assessment of baseline knee alignment, the participant stood with feet facing forward directly underneath corresponding acromion processes and weight evenly distributed. The first axis was measured from ASIS to the knee joint center (defined as the center point between femoral epicondyles in the frontal plane). The second axis was measured from the knee joint center to the ankle joint center (defined as the center point between the medial and lateral malleolus in the frontal plane). All participants presented with varus knee alignment of ≥ 2° on the dominant limb. Mass(kg) and height (m) measurements were measured and used to calculate BMI. Once eligible, participants determined a self-selected walking speed by walking between 2 sets of infrared timing gates (TF100, TracTronix). Starting approximately 5 steps before the first timing gate, participants were instructed to walk at a speed described as "comfortable walking over a sidewalk"[32]. Each participant completed 5 trials and the average walking speed was calculated.

Pre-loading Protocol

Participants reported to the laboratory at the same time of day (±2 hours) for both sessions to account for diurnal variations within the cartilage[17]. Upon arrival, participants sat on a treatment table in the long-sit position with knees fully extended for 45 mins to allow time for cartilage reformation[15].

Ultrasonographic Assessment of the Femoral Articular Cartilage

While seated with their back up against the wall, participants flexed their knee to 140° measured using 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[15]. A LOGIQe US system (General Electric Co., Fairfield, CT) with a 12MHz linear probe was used to image both the medial and lateral femoral cartilage. The probe will be placed transversely in line between the medial and lateral femoral condyles just superior to the patella and rotated to maximize reflection of the articular cartilage[26]. A transparent grid was placed over the US screen to improve reproducibility of the US image[15]. 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 across US assessments. Three images were collected of each knee at each time point. Following each loading condition, the participant was placed in the same position as the pre-loading US assessment using the tape measure. Three images of the femoral cartilage were recorded from each knee. All post-walking images were captured within 5 minutes of the loading protocol.

Cartilage Loading Protocol

Immediately following pre-test ultrasound assessments, participants were transferred from the table to a wheelchair in order to minimize knee loading not related to the walking condition. During the braced walking condition, a valgus unloader brace (Össür Unloader One®, Össur Americas, Orange County, CA) was fitted by a 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. The participant took 30 steps to adjust to the brace. Adjustments were made as needed if the participant determined the fit was uncomfortable or too loose. The participant took 30 more steps. This was completed four times in total. The participant was transferred to and from the treadmill via wheelchair to control the amount of cartilage loading.

Control Protocol

In the unbraced condition, the participant repeated the brace protocol except that the participant was not fitted with an unloader brace while seated. The participant took 120 steps to keep the number of steps consistent across trials before being transferred to the treadmill. The participant remained unbraced for the entire trial.

Loading Protocol

Participants maintained the self-selected walking speed for 5000 steps on a treadmill (4Front, WOODWAY, Waukesha, WI). Self-selected speed was kept the same across both conditions. Participants walked for 1 minute to adjust to the treadmill. Steps were then counted for 1 minute, and the time necessary to complete 5000 steps was calculated (5000 divided by number of steps per minute).

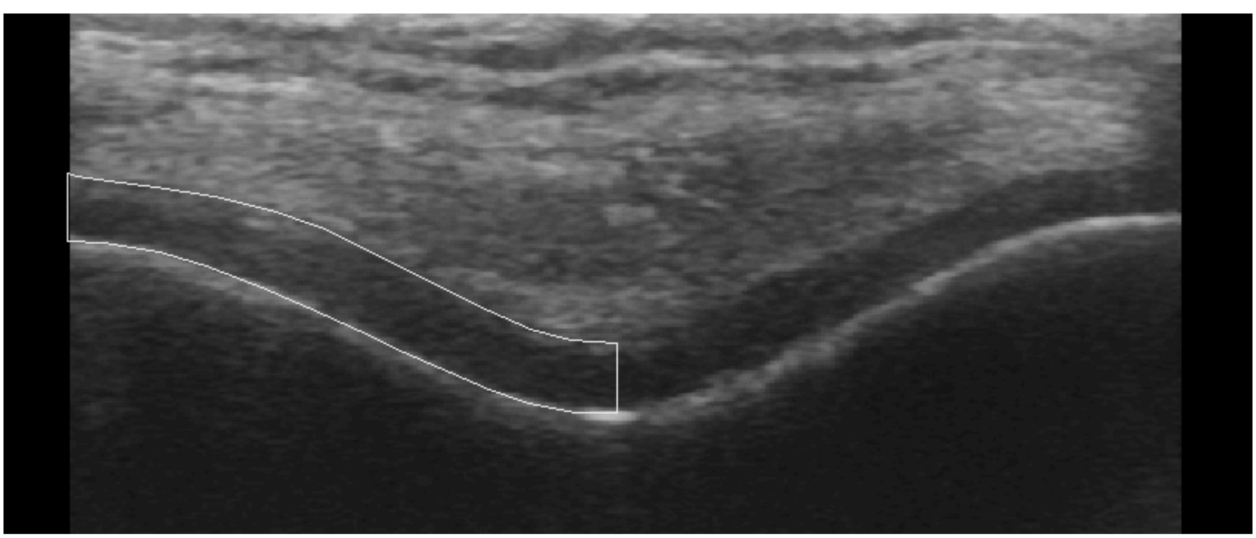
Ultrasonographic Image Analysis

All US images were analyzed with the ImageJ software (National Institutes of Health, Bethesda, MD). Medial compartment cartilage area (MCCA) is our primary outcome measure. Values for MCCA were obtained for each of the three images of the dominant limb at each time point (pre and post-walking) and averaged for statistical analysis.

Medial Compartment Cartilage Area

All images were analyzed by a single trained investigator. The femoral cartilage was divided into medial and lateral sections by identifying the midline at the most inferior point of the intercondylar groove. The MCCA was outlined with a polygon function as our primary outcome variable of interest (Figure 1). The area (in square millimeters) of the section was measured. Percent change scores ([baseline -post]/baseline *100) for each cartilage outcome measure were calculated.

Figure 1. Cartilage area measure for medial femoral condyle.



Statistical Analysis

Primary Analysis

Demographic information including means and standard deviations were collected for the entire cohort (Table 1). Intersession intra-class correlation coefficients (ICC) were calculated to assess the reliability of baseline measures for cartilage area. ICC values were classified as weak (< 0.5), moderate (0.5–0.69), or strong (≥ 0.7)[34]. Two-tailed paired samples t-tests were used to compare percent change scores for the braced and unbraced conditions for each outcome measure. Differences with a P value ≤ 0.05 were considered significant. All statistical analyses were performed using SPSS (v21.0; IBM Corporation).

Post Hoc Analysis

Not all subjects displayed medial compartment articular cartilage deformation during the unbraced walking condition. We split the original cohort into 2 groups: deformers, defined as individuals who demonstrated a change in MCCA of more than the previously described MDC (≥ 1.58 mm^2)[35], and non-deformers, defined as those who did not demonstrate a deformation of 1.58 mm^2 in MCCA following 5000 steps of unbraced walking. Two-tailed paired sample *t*-tests were conducted to determine if there were differences between braced and unbraced conditions for the deformers and non-deformers. 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.

CHAPTER 4

Twenty-four healthy individuals with varus knee alignment (62.5% female, 1.70 ± 0.07 m, 66.71 ± 12.85 kg, Table 2) completed both trials. Measures of baseline cartilage area for the medial condyle (ICC = 0.97) demonstrated acceptable reliability (ICC ≥ 0.7) between sessions.

Table 2. Demographic characteristics

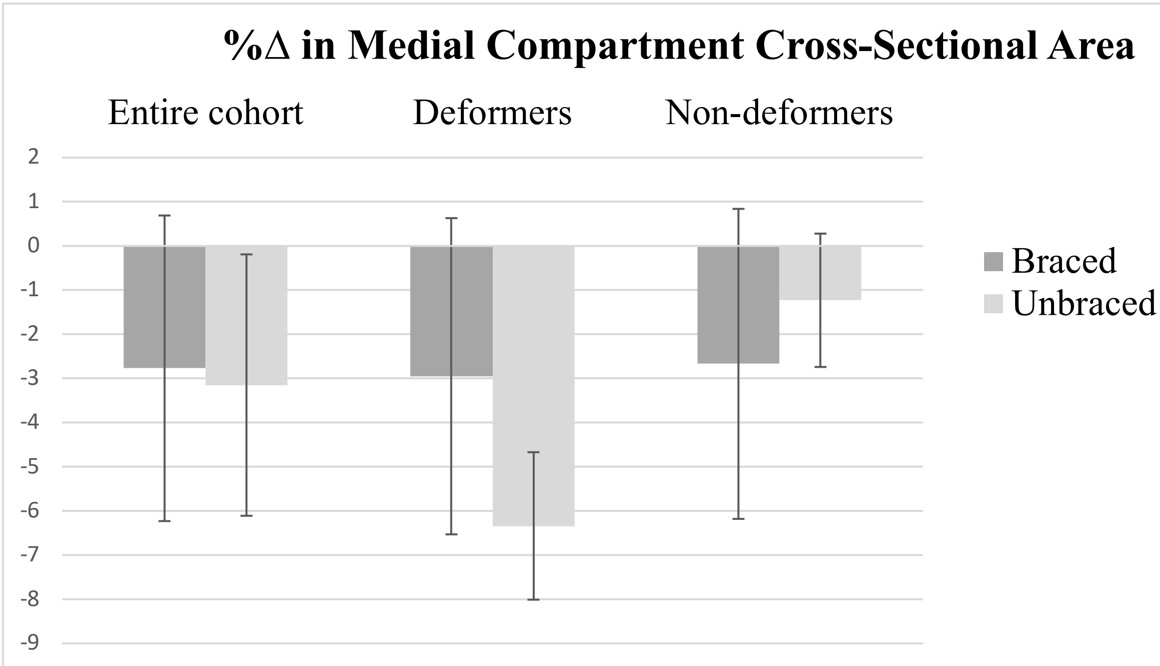
	Entire cohort	Deformers	Non-deformers
Participants	9 male, 15 female	3 male, 6 female	6 male, 9 female
Age	20.58 ± 2.80	19.56 ± 1.74	21.20 ± 3.17
Height (m)	1.70 ± 0.07	1.71 ± 0.07	1.69 ± 0.08
Mass (kg)	66.71 ± 12.85	65.14 ± 10.46	67.64 ± 14.36
BMI	22.99 ± 3.07	22.17 ± 2.11	23.49 ± 3.49
Knee varus (°)	3.07 ± 1.11	2.96 ± 1.11	3.13 ± 1.14
Walking speed (m/s)	1.35 ± 0.17	1.34 ± 0.12	1.35 ± 0.19

For our primary analyses, we did not find significant differences between percent change for cartilage area for the medial condyle ($t_{23} = 0.392$, $p = 0.699$) between braced and unbraced conditions. Because our planned comparisons did not reveal significant findings, we ran a *post hoc* analysis to further analyze the data set. In our *post hoc* analysis, deformers demonstrated significantly less percent change for cartilage area during the unbraced condition compared to the braced condition for the medial condyle ($t_8 = 2.679$, $p = 0.028$). For the non-deformers, we did not find any difference between cartilage area percent change for the medial condyle ($t_{14} = -1.314$, $p = 0.210$) between braced and unbraced conditions.

Table 3. Cross-sectional area cartilage change

			Baseline	Post	
			Absolute (mm)	AbsoluteΔ (mm)	%Δ
	Participants	Condition	Medial	Medial	Medial
Cross-sectional area (mm2)	Entire cohort (n = 24)	Unbraced	45.80 ± 5.11	-1.38 ± 1.31	-3.15 ± 2.96
		Braced	45.98 ± 5.08	-1.24 ± 1.60	-2.77 ± 3.46
	Deformers (n = 9)	Unbraced	44.12 ± 5.48	-2.76 ± 0.69	-6.34 ± 1.67
		Braced	43.68 ± 4.82	-1.25 ± 1.50	-2.95 ± 3.58
	Non-deformers (n = 15)	Unbraced	46.82 ± 4.77	-0.55 ± 0.75	-1.23 ± 1.51
		Braced	47.36 ± 4.87	-1.23 ± 1.71	-2.67 ± 3.51

Figure 2. Percent change in medial compartment cross-sectional area



CHAPTER 5

Contrary to our original hypothesis, we did not find any difference between the braced and unbraced conditions for cartilage deformation in the entire cohort. After dividing the cohort into two subgroups, we did find that individuals who surpassed the MDC during normal or unbraced walking demonstrated less deformation during the braced condition. While prior studies have identified reductions in KAM during walking with an unloader brace[12,27,29], the current study provides additional evidence to suggest that unloader braces reduce femoral articular cartilage deformation in some individuals who normally undergo femoral cartilage deformation during walking. We also found a subgroup of cartilage deformers demonstrated similar MCCA percent change as previous studies.[15,35] Our study provides important information regarding the capability of a valgus unloader brace to diminish strain on femoral articular cartilage in individuals who normally undergo cartilage deformation during walking.

Conversely, a large proportion of the cohort (n=15) did not deform greater than the previously demonstrated MDC in medial cartilage area[35]. It is possible other individuals experienced femoral cartilage deformation and we were unable to measure it with the single slice of cartilage captured with our US technique. Our method for US image assessment captures primarily a portion of the anterior femoral articular cartilage[35]. Any deformation occurring posteriorly on the femoral cartilage was not assessed with our technique. We also cannot assume all individuals respond to cartilage loading in the same manner. Although our sample was young and healthy subjects, that does not mean each subject’s cartilage was loaded or responded to load in the same manner. The loading protocol of 5000 steps used in our study may have been either too great or insufficient to cause significant deformation in some subjects. Further, rate of loading has been shown to impact cartilage deformation[36] and was not accounted for in our study.

Individuals who deformed with unbraced walking did not deform with braced walking. Intersession reliability was strong across conditions indicating baseline measures were similar between days. Therefore, differences in deformation between conditions may be best attributed to our brace intervention. Our findings suggest that unloader braces may diminish deformation on the articular cartilage possibly by lessening the load on the medial tibiofemoral joint in healthy individuals. We can hypothesize the unloader brace may positively affect cartilage health in individuals who demonstrate deformation following 5000 steps. Unloader braces have already been used on individuals with cartilage pathology and shown significant reductions in pain and function.[29] More research is needed to determine the impact of unloader braces on cartilage deformation specifically in these individuals.

The results of our study support the use of a 5000 step walking protocol as a cartilage stress test in some individuals. For those that deform past the MDC during unbraced walking, the unloader brace may be an effective intervention. Therefore, this stress test has potential clinical use in identifying candidates who will respond positively to being mechanically unloaded at the knee. It is possible that clinicians may evaluate the effectiveness of the intervention prior to prescribing these braces for patients. Previously, the impact of unloader braces on femoral cartilage was unknown. All prior research used the KAM as a surrogate measure for medial compartment knee load but did not measure deformation after a standard stress test.[12,29-30] Our study was the first to use US to evaluate an acute effect of an unloader brace directly on cartilage deformation.

While the findings of this study encourage further research into this area, there are several limitations to consider. First, all findings were in young, healthy subjects without history of significant knee pathology or surgery. Future studies should recruit participants that are either at-risk or experiencing symptomatic knee OA. Further, the sample size may be small, especially after being divided into the deformers (n=9) and non-deformers groups (n=15). A larger sample of individuals that deform greater than the MDC may more accurately reflect the population as a whole. Another important consideration is that only one segment of the femoral articular cartilage was captured with US. Femoral cartilage deformation may not be accurately captured in individuals who deformed in different parts of their femoral cartilage. Multiple knee biomechanics can also impact cartilage deformation in our population. While we screened for static knee alignment, no further biomechanical measures were included in our study. It is unclear how the unloader brace impacts knee biomechanics. Further, because there were only two time points at which we captured US images, individuals may also have had varying responses to our loading protocol (5000 steps) that were not evaluated. Future studies may seek to evaluate the effect of unloader braces following shorter or longer distances than what was evaluated in the current study. These limitations demonstrate the need for a wider body of evidence to further support the findings of this study.

Overall, there was no significant difference in MCCA percent change between the braced and unbraced conditions for the entire cohort. The unloader brace did reduce the amount of medial compartment femoral cartilage deformation in individuals who demonstrated cartilage deformation exceeding the MDC during the usual walking condition. We can conclude the unloader brace may impact cartilage strain in young healthy individuals with static knee varus who demonstrate measurable deformation in the medial femoral cartilage during walking.

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