Functional Evaluation of a Personalized Orthosis for Knee Osteoarthritis: A Motion Capture Analysis

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Orthotic treatments for knee osteoarthritis (OA) typically rely on simple mechanisms such as three-point bending straps and single-pin hinges. These commonly prescribed braces cannot treat bicompartmental knee OA, do not consider the muscle weakness that typically accompanies the condition, and employ hinges that restrict the knee's natural biomechanics. Utilizing a novel, personalized joint mechanism in conjunction with magnetorheological dampers, we have developed and evaluated a brace which attempts to address these shortcomings. This process has respected three principal design goals: reducing the load experienced across the entire knee joint, generating a supportive moment to aid the thigh muscles in shock absorption, and interfering minimally with gait kinematics. Two healthy volunteers were chosen to test the system's basic functionality through gait analysis in a motion capture laboratory. Combining the collected kinematic and force-plate data with data taken from sensors onboard the brace, we integrated the brace and leg system into a single inverse dynamics analysis, from which we were able to evaluate the effect of the brace design on the subjects' knee loads and moments. Of the three design goals: a reduction in knee contact forces was demonstrated; increased shock absorption was observed, but not to statistical significance; and natural gait was largely preserved. Taken in total, the outcome of this study supports additional investigation into the system's clinical effectiveness, and suggests that further refinement of the techniques presented in this paper could open the doors to more effective OA treatment through patient specific braces. [DOI: 10.1115/1.4051626]

1 Introduction

1.1 Knee Osteoarthritis and Bracing. Osteoarthritis (OA) is a degenerative condition characterized by serious and localized degradation of the cartilage that protects the bony surfaces along which joints move. The knee is one of the most common joints to be affected by OA. It is estimated that 12.1% of the population over 60 has symptomatic knee OA, with that number rising to 27% after age 75 [1,2]. As the articular cartilage inside the knee is compromised, its ability to cushion the bone of the joint is lost, causing significant pain to those suffering from the disease. In addition, OA is known to present with weakness of the major knee extensor muscles (quadriceps) as well as reduced joint stability [3,4]. This leads to a marked drop in sensorimotor function of the limb, encompassing both proprioception and degree of voluntary muscle contraction [5]. Taken together, this collection of symptoms greatly inhibits both balance and mobility, and can significantly decrease quality of life for those suffering with advanced stages of the disease.

The two factors with the most relevance toward severity of symptoms and further worsening of the condition are quadriceps weakness and the magnitude of the force experienced by the joint during gait [4–8]. The contribution of a larger force to the condition is clear—it will degrade cartilage more quickly and cause a greater degree of irritation. Muscle weakness acts to increase the effects of the experienced force. In individuals with knee OA, the inability to adequately support knee flexion due to quadriceps weakness corresponds to a decrease in the degree of flexion (known as excursion) during normal walking [9–11]. This has two outcomes. First, a straight-legged gait increases the mechanical impulse felt at the tibiofemoral interface by decreasing the duration of loading response (the phase of gait in which the knee flexes to absorb the weight of the body in preparation for single-legged stance). Second, lower than normal excursion fails to spread the load across the articular surface, focusing it in a much smaller area. These effects further increase both the rate of cartilage deterioration and the degree of irritation in that specific location.

Bracing has long been the primary strategy for noninvasive corrective intervention. The common presentation of the condition in either the medial or lateral compartment of the knee has focused OA brace technology on one particular strategy of symptom relief [2]. Unloader braces use straps configured to apply three-point bending forces in an attempt to relieve the affected compartment by shifting some of the load to the less diseased condyle. These braces can provide a small improvement in pain when compared to control braces that align the knee neutrally [12,13], but their use is frequently discontinued, with patients citing ineffective relief and discomfort [14]. Some of the blame for both of these complaints can be placed on the poor ability of common brace hinges to accommodate and follow the natural motion of the user's knee joint [15]. Approximations of this motion used in orthoses, such as those created by single or double pin joints, can produce misalignment of the knee and brace joint centers, leading to relative motion between brace and leg. Even advanced hinge mechanisms, e.g., four-bar mechanisms or gear systems, can introduce shearing forces and induce abnormal ligament lengths [16]. Unloader braces are also unable to treat multicompartmental OA, which for severe cases, particularly among candidates for eventual arthroplasty surgery, can mean they are not a viable treatment option [17]. Additionally, the characteristic muscle weakness of knee OA is not treated by these braces beyond their incidental stabilizing effect.

Recent developments in OA bracing have focused largely on iterating on the three-point unloader concept. Some have attempted to provide more individualization of treatment, such as

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alterations to the basic brace designs that allow in situ adjustment of fit and alignment characteristics [18] or changes to the degree of corrective moment applied [19]. More novel bracing ideas are rarer. Laroche et al. reported on their development of a "distraction-rotation" brace that attempts to augment the effectiveness of a three-point valgus brace by also introducing external rotation of the lower leg [20]. Unfortunately, it appears that no appreciable difference in limb function was reported between it and a standard unloader brace [21]. Others have focused on producing hinge mechanisms that try to account for the knee's complex motion. Bertomeu et al. used a crossed four bar linkage to approximate knee motion, resulting in a 93% decrease in misalignment from a standard single-pin hinge [15] and Wang et al. combined a cam and slider to minimize internal forces created by the orthosis [22]. Solutions such as these attempt to find an optimal solution for the average knee motion, but they can still suffer from misalignment issues and have yet to be adopted by commercial OA braces.

1.2 Brace Design Overview. To address some of the above shortcomings, we have designed, produced, and tested a novel, quasi-passive knee orthosis that can be tailored to a specific patient's pathology. The device consists of three systems. First, a novel joint mechanism, combining a four-bar linkage and prismatic joint into a two-degree-of-freedom hinge, was designed through motion capture analysis to better follow the motion of the knee and allow for a more natural gait than hinge designs common to current braces. Second, a passive support system is able to accept and redirect load around the knee, thereby reducing the contact force experienced by both condyles of the knee joint. This passive support system comprises spring elements incorporated into the slider joints on both sides of the brace, providing the system with the ability to unload both condyles of the knee joint. The two previous elements combine to act in tandem as a single system, which we have termed a "hybrid joint mechanism." Finally, a controllable magnetorheological (MR) element provides a supportive torque about the knee during flexion. This torque supports the quadriceps muscles during the critical loading response phase of gait, promoting knee flexion and increasing leg stability. Due to its modular nature, this system is highly customizable, and can be tailored to a specific user's gait characteristics and pathology. An overview of this design was first presented in Ref. [23], and an examination of the hybrid joint mechanism, its faithfulness to natural knee kinematics, and its customizability to a given user can be found in Ref. [24]. A two-dimensional representation of the general design concept is shown in Fig. 1.

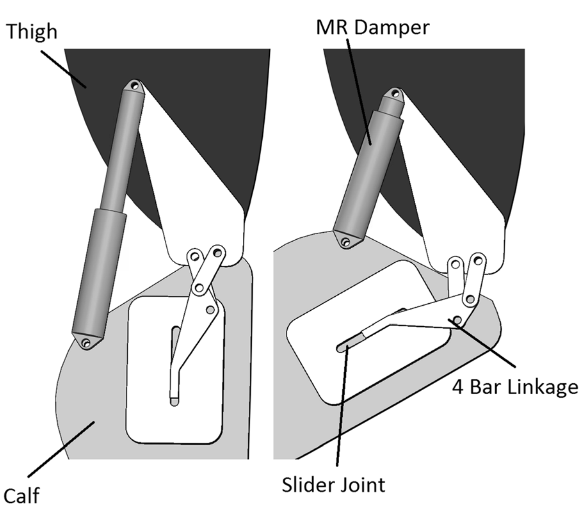

Fig. 1 Two-dimensional layout of design concept

As previously alluded to, the motion of the knee joint in the sagittal plane is a complicated mixture of rolling and sliding along a noncircular element. Therefore, common approximations such as single or double pin joints are inaccurate—the knee's center of rotation can move several centimeters relative to the underlying knee anatomy during flexion [25,26]. The mechanism linking the calf and thigh portions of the orthosis must be able to accurately follow this motion. By allowing relative motion in one degree-of-freedom, namely, proximal-distal translation between the mechanism and the calf, we find that the coupler of a 4R four-bar linkage can effectively maintain alignment with the calf's body vector to within a few degrees [24]. This translation is facilitated by a prismatic joint linking the coupler of the 4R linkage to the calf portion of the orthosis. Through careful design of the four-bar and prismatic pair, the motion characteristics of the slider joint can be selected to our advantage. We introduce a spring element into this joint and tailor the mechanism such that it compresses the spring only at knee angles associated with stance. In other words, when the knee is extended, a traction force is produced across the knee joint which counters a portion of the force created during stance by the weight of the body.

Inverse dynamics is a technique common in the fields of biomechanics and gait analysis [27]. It combines measured kinematics and ground reaction forces with inertial properties to compute joint forces and moments. Using motion capture and force-plate data, inverse dynamics is solved on the lower body using a link-segment model common to gait analysis. From this, the joint contact force over the gait cycle can be calculated. Next, a target maximum allowable force can be selected. Combining the spring compression rate resulting from the design of the mechanism with this target maximum force value yields the desired force versus displacement curve for the spring. The resulting spring characteristics, although highly nonlinear, can be approximated by a titanium leaf spring whose specific geometric parameters were discovered via genetic algorithm optimization. This process is described in slightly more detail in Ref. [24].

To address muscle weakness, a supportive moment is applied about the knee center during loading response by a set of MR dampers. This moment acts about the same axis and in the same direction as quadriceps activation, and the resulting support should allow more stability at greater knee flexion angles, thereby increasing excursion of the joint during stance. The MR fluid used in such dampers is a suspension of iron microspheres in a grease or oil base. When subjected to a magnetic field, these particles align to greatly increase the viscosity of the fluid. The degree of increase corresponds to the strength of the magnetic field, and through the use of an electromagnet the viscosity can be accurately controlled. The dampers used in this orthosis have been optimized for maximum magnetic flux at the electromagnet surface, subject to strict volume constraints to minimize their size and weight. A finite element magnetics software package (FEMM 4.2) was interfaced with MATLAB to perform numerical optimization on the design parameters of the dampers.

Taken together, this combination of subsystems provides both a supportive moment and a load-reducing force to the knee joint. The specific effects on the joint interface can be seen in Fig. 2. The dampers are positioned with their moment arms behind the knee center, providing a moment that supports eccentric flexion. The force generated by the spring in the calf portion of the brace is passed through the brace to the thigh, creating an alternate load path.

A favorable evaluation of these subsystems in a prototype device—in other words, a demonstration of their ability to accomplish the three principal design objectives—could lead to more effective and more personalized treatment for advanced and bicompartmental cases of knee OA.

2 Evaluation Methodology

After validating simulation results through the analysis of a simple bench-top device, a prototype orthosis was fabricated in

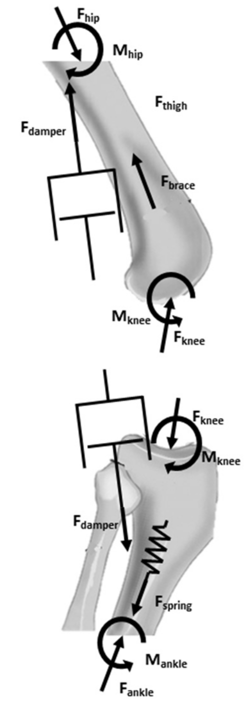

Fig. 2 Knee forces and moments

full for evaluation (Fig. 3). While this initial prototype does appear somewhat robust for the application (at 830 g, its weight is near the higher end of commercial knee orthoses), that robustness is not without purpose. Ease of modification was of considerable importance, as was the requirement for flat, visible surfaces onto which reflective markers could be placed for the motion capture system. As will become clear, precise knowledge of the location of these markers with respect to the brace's underlying geometry was vital to this investigation's methodology. This would have been made difficult or impossible by a more ergonomic and/or flexible approach to the design of the prototype.

Before exploring the brace's effectiveness in treating pathological patients, we must first examine its functional performance. In other words, we are investigating the behavior of the three subsystems to determine if they act as designed rather than evaluating the clinical effectiveness of the brace or its ergonomic impact. The criteria by which the brace's performance will be evaluated are: the resulting reductions in knee loading and moment, the brace's ability to support shock absorption, and the degree to which the brace affects the characteristic angles the knee reaches during gait.

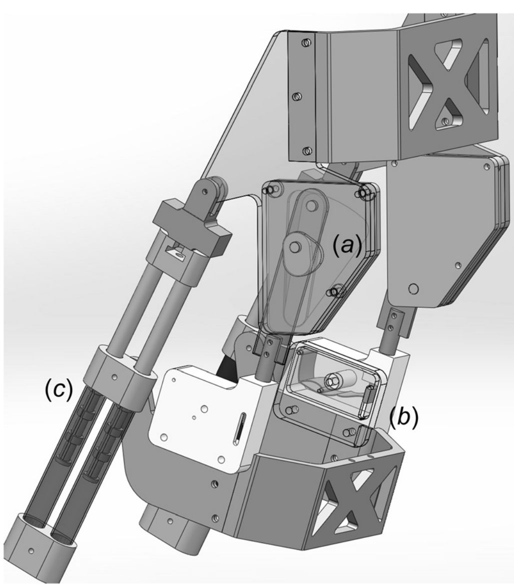

Fig. 3 Design overview: (*a*) joint mechanism, (*b*) spring support system and (*c*) MR dampers

An optical motion capture system (VICON NEXUS 2.0 with four Bonita 10 cameras and eight Bonita 3, Vicon, Centennial, CO) was used to measure three-dimensional kinematic data of the subjects during gait, encompassing the segments of the right leg and pelvis as well as the rigid portions of the brace. A force plate (Bertec 4060-07, Bertec, Columbus, OH) captured the three-dimensional forces, moments, and center of pressure measured at the contact surface between foot and ground. On-board the brace, two inertial measurement units (MPU-6050, Addicore, San Diego, CA), primarily used in the control system of the dampers, recorded three-axis acceleration and gyroscopic data of the brace segments, digitized to 16-bits. Additionally, force transducers (Transducer Techniques MLP-75, Transducer Techniques, Temecula, CA) measured the force produced by the dampers, digitized to 10-bits. Both sets of values were saved locally to the brace electronics. Post data collection, the data taken from the brace and the data taken from the motion capture system were aligned to produce a complete picture of the study.

Following IRB approved protocols, two healthy volunteers were chosen as motion capture subjects for the functional testing of the brace: subject 1, a 33-year-old male standing 175 cm and weighing 87.2 kg; and subject 2, a 29-year-old male standing 170 cm and weighing 83.9 kg. Neither possessed a history of pathological gait. The brace was worn on the right leg and six body segments were tracked: the right foot, right calf, right thigh, pelvis, upper brace portion, and lower brace portion. At least four reflective markers were placed on each segment to allow their tracking in three dimensions should one marker momentarily drop from camera view. Testing conditions were chosen to mimic natural, flat-surface gait as closely as possible—each subject walked at a comfortable, repeatable pace (dictated by metronome) through the capture area such that the right foot landed on the force plate in a natural manner (i.e., the stride lengths remained constant before and after contact with the plate). Any trials that did not meet these criteria were excluded and retaken. Three sets of data were taken under three different conditions: 1—a control state without the subjects wearing the brace, 2—wearing the brace but leaving the dampers unpowered and inactive, and 3—wearing the fully activated brace.

These data sets allow examination of the brace subsystems as well as their influence on the subjects' gait mechanics. Data from the brace's onboard sensors can be used in conjunction with the motion capture and force plate results to integrate the brace segments and reaction forces into an inverse dynamics analysis. From this, direct calculation of the brace contributions to the reaction forces and moments at the knee becomes possible.

Some assumptions and mathematical manipulations are necessary to bring our data into the form required for use in inverse dynamic analysis. First, the forces generated by the springs were not directly measured. However, the three-dimensional orientation of the brace segments with respect to each other is known precisely, and that orientation dictates the springs' degree of compression. In combination with the measured force versus displacement curves of the springs, their force contributions were calculated. Second, the knee centers of our subjects were obscured by the brace and could not be explicitly tracked during motion capture. To get around this limitation, their locations were inferred with respect to leg anatomy, based on measurements taken of the subjects' leg segments. Knee marker points were then added to the three-dimensional kinematic data in postprocessing, using tracked anatomical marker points as reference. Additionally, the centers of mass, radii of gyration, and moments of inertia of the leg segments were calculated using collected anthropometric data tables combined with measured physical characteristics such as body weight and segment length [27]. All measured kinematics

Table 1 Knee force peak comparison

	First knee force peak (N)			Second knee force peak (n)		
	Absolute	Change from control	Change from inactive	Absolute	Change from control	Change from inactive
Subject 1						
1. Control: no brace	902.3			986.3		
2. Brace, dampers inactive	804.8	**−97.5***		938.8	**−47.5***	
3. Brace, fully active	861.3	−41 ($p = 0.07$)	+56.5 ($p = 0.06$)	958.7	**−27.6***	+19.9
Subject 2						
1. Control: no brace	846.1			862.5		
2. Brace, dampers inactive	710.6	**−135.5***		761.5	**−101***	
3. Brace, fully active	711.7	**−134.4***	+1.7	744.5	**−118***	−17

An asterisk indicates significance to 95% confidence.

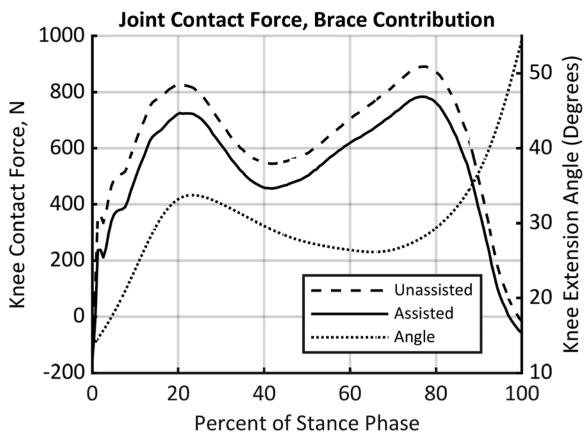

Fig. 4 Knee contact force during stance

and reaction forces were projected onto the sagittal plane (assumed to be stationary and aligned with the subjects' direction of travel in each trial) before performing the analysis. Finally, individual muscle forces were not modeled; muscles pertaining to knee motion were assumed to act in such a way as to generate a single extension/flexion moment about the knee.

The data taken via to the described methodology, and subjected to inverse dynamics analysis according to the above assumptions and manipulations, supplies us with a complete sagittal plane picture—both kinematic and kinetic—of the leg and brace during natural, straight-line gait on a flat surface. It is this plane that holds the greatest interest to our investigation, and from here that we begin our examination of the data.

3 Results and Discussion

Of particular importance to our goal of pain relief is the magnitude of the contact force experienced by the knee. Two distinct force peaks are reached during the gait cycle—the first during loading response and the second during push-off. Table 1 displays the values of these peaks across the different parts of the study. In all but one of the brace trials (subject 1, test 3—fully active brace), we see a significant reduction in both values.

Figure 4 displays knee contact force during stance for one of subject 2's fully active tests, illustrating these peaks more clearly. The 'unassisted' values can be thought of as what the knee would experience in the absence of the brace, and were calculated by omitting the effects of the brace on knee loading and assuming negligible inertial effects from the brace segments. Such a plot is useful as an illustrative example—by comparing the two curves, one can infer the overall force contribution made by the brace's support systems, rather than just at the critical peaks recorded in Table 1.

Also of interest are the moments generated by the leg during stance and swing. The device was designed to provide a supportive moment during stance as well as to interfere minimally with the remainder of gait. Accordingly, we would like to see a reduction in the required maximum extension moment during midstance and a minimal change during swing. Table 2 presents the values observed during the study. Examined in this way, the only statistical significance shown is, unexpectedly, in the wrong direction. That is to, say, subject 1 was required to generate a higher maximum extension moment in his fully active tests during both stance and swing.

Once again, a representative plot is useful to visualize the contribution of the damper system to the extension moment during stance. Figure 5 depicts a sample from subject 2's fully active tests. While not of statistical significance at the peaks, the overall reduction in required knee moment due to the brace can be seen.

To evaluate the brace's effect on the subjects' natural gait patterns, we can examine the angular trajectory the knee takes through the gait cycle. In particular, the extreme angles reached when the leg straightens just before heel-down (minimum flexion) and when it bends during swing (maximum flexion) can be informative. In Table 3 we see that both subjects' trends agree—a slightly more bent leg at heel-down and, during the inactive trials,

Table 2 Maximum extension moments

	Extension moment midstance (nm)			Extension moment swing (nm)		
	Absolute	Change from control	Change from inactive	Absolute	Change from control	Change from inactive
Subject 1						
1. Control: no brace	46.9			−38.1		
2. Brace, dampers inactive	40.5	−6.4		−47.2	−9.1	
3. Brace, fully active	79.6	**+32.7***	**+39.1***	7.2	**+45.3***	**+54.4***
Subject 2						
1. Control: no brace	55.7			−43.1		
2. Brace, dampers inactive	51.1	−4.6		−41.0	+2.1	
3. Brace, fully active	43.3	−12.4	−7.8	−49.4	−6.3	−8.4

An asterisk indicates significance to 95% confidence.

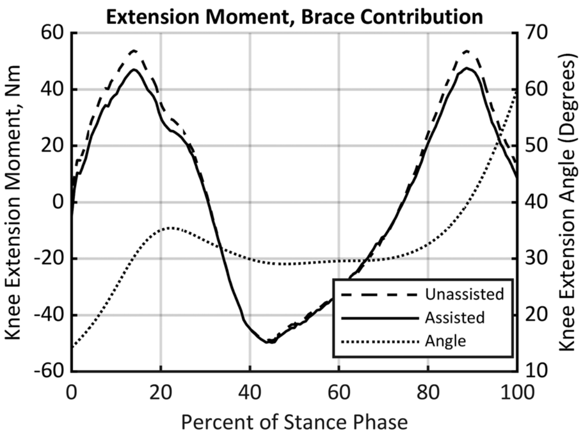

Fig. 5 Extension moment during stance

a slightly straighter one midswing. Interestingly, the activation of the damper appears to restore some of the lost knee flexion during swing.

The above presented data show that the knee loading was significantly reduced in seven of the eight force peaks studied, and subject 2 displayed a 16% reduction in knee force experienced during loading response. This corresponds to a decrease of approximately 135 N, which is just over 90% of the target reduction. As knee load is a primary predictor for both pain and further worsening of symptoms [6,7], this result reveals the promise of our design. The second objective, that of providing a supportive moment about the knee during stance, was met with more ambiguous results. Subject 1's results were anomalous, but subject 2 displayed a clear trend toward showing the supportive moment that the brace was designed to produce. The subject displayed a reduction in required maximum moment (22% when comparing the fully active dataset to the control, and 15% when compared to the inactive damper dataset), although high standard deviations in both the control and damper tests prevent any finding of statistical significance. Additionally, the recorded forces generated by the dampers only approached 50% of their designed maximum, indicating a technical issue that once overcome should lead to an appreciable increase in effectiveness. A hypothesis as to the nature of this issue will be touched on in the coming paragraphs. The final goal, that of minimal interference with gait, was successful during swing with the fully active brace, but not at heel-down. This was as predicted—the increases to the minimum knee angle (immediately preceding heel-down) are an unavoidable effect of the springs. Their compression is initiated by knee extension, and resistance to that extension as they compress was to be expected. Small changes (as seen in subject 1) are unlikely to cause significant effects—knee angle at heel-down has not been reported as adversely affecting symptoms of knee OA.

Although both subjects displayed reductions in at least one force peak, there were several interesting differences between the two. Subject 2 displayed markedly higher force reduction (Table 1) than his flexion angles at heel-down (Table 3) would suggest. Due to the nature of the design (the prismatic joints compress the springs as the knee extends), a slightly bent leg at heel-down would imply incomplete spring compression. This discrepancy is illustrated in Fig. 6 with selections from both subjects' fully active tests. Displayed in the figures are the measured values of the compression of the medial and lateral springs beginning shortly before and ending shortly after stance. The "theoretical" spring compression is what we would expect to see, taken from simulations conducted using the knee kinematics recorded during the trials combined with known brace function. Subject 2's unexpected results can likely be explained by variations in fit and location. Either the mechanism was incorrectly positioned with

Table 3 Knee flexion extremes during gait

	Flexion at heel-down (deg)			Flexion midswing (deg)		
	Absolute	Change from control	Change from inactive	Absolute	Change from control	Change from inactive
Subject 1						
1. Control: no brace	0.2			74.5		
2. Brace, dampers inactive	3.2	**+3.4***		67.1	**–7.4***	
3. Brace, fully active	3.7	**+3.9***	+0.5	75.4	+0.9	**+8.3***
Subject 2						
1. Control: no brace	3.6			74.4		
2. Brace, dampers inactive	10.7	**+7.1***		69.1	**–5.3***	
3. Brace, fully active	9.8	**+6.2***	–0.9	72.8	–1.6	**+3.7***

An asterisk indicates significance to 95% confidence.

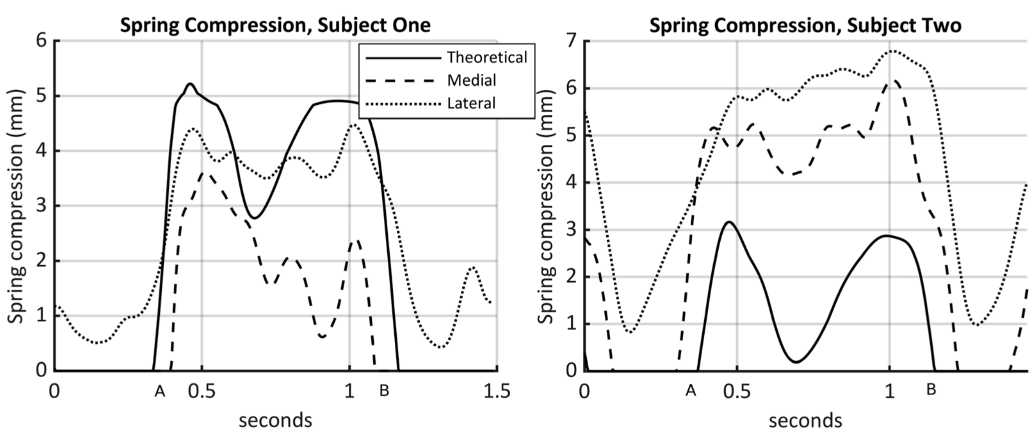

Fig. 6 Spring compression comparison: (*a*) heel-down and (*b*) toe-off

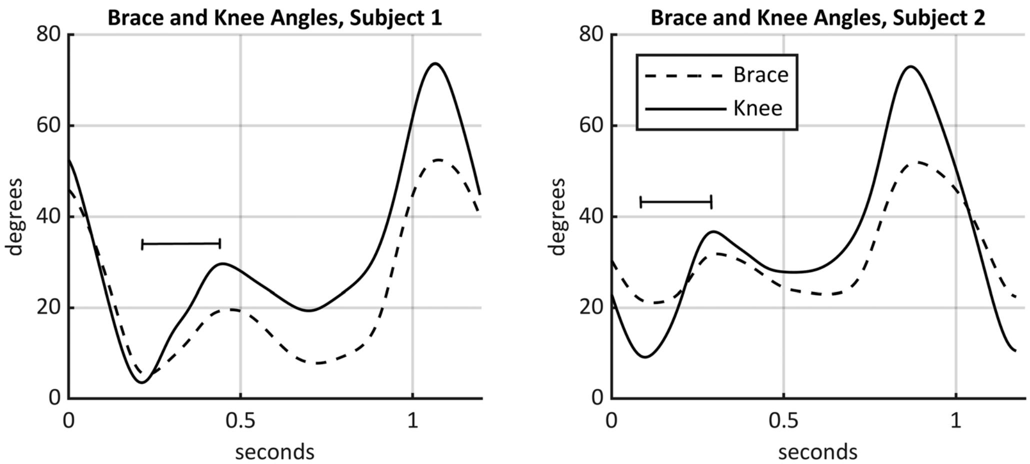

Fig. 7 Knee and brace angles during gait. The marked intervals indicate loading response.

Table 4 Flexion during loading response

	Maximum stance knee flexion (deg)		
	Absolute	Change from control	Change from inactive
Subject 1			
1. Control: no brace	33.2		
2. Brace, dampers inactive	26.4	**–6.8***	
3. Brace, fully active	30.7	–2.5	**+4.3***
Subject 2			
1. Control: no brace	32.1		
2. Brace, dampers inactive	32.4	+0.3	
3. Brace, fully active	34.1	+2.0	+1.7

An asterisk indicates significance to 95% confidence.

respect to the leg when subject 2 put on the device, or—more likely—it was worn with an excessive level of spring precompression. The latter possibility would also account for subject 2's inability to reach full knee extension before heel-down, as displayed in Fig. 7—the spring prismatic joints could have approached the limits of their travel too far in advance of the foot's contact with the ground.

Additional variation from the expected spring compression values, such as that presented by subject 1 in Fig. 6, can be explained by the deformation of the elements between brace and leg. In other words, the padding of the brace and the soft tissue of the leg combine to produce an effect whereby the motion of the brace does not perfectly match that of the leg. Figure 7 compares the flexion angle of the knee during gait to the angle made by the brace, and further illustrates this possibility. We see that the change in brace angle lags behind the change in knee angle—an effect of soft elements absorbing knee flexion/extension before the brace itself begins to move.

While it would be ideal to see each subject's brace angle perfectly match his knee angle, a mismatch at any given point does not necessarily imply imperfect tracking—some degree of offset will always be present based on the initial wearing position of the brace. The moderate difference in brace angle trajectories displayed by the subjects in Fig. 7 can be explained by these two factors—a difference in initial brace position producing a small offset, and variations in soft tissue and padding producing a slightly different response.

This same effect can be seen in the axial movement of the brace with respect to the leg. In response to the forces generated by the springs there is some deformation of the underlying soft elements, causing the brace to be pushed axially along the leg while the springs are engaged. This effect was anticipated, and effort was made to apply the brace with the springs appropriately compressed at full knee extension. While not trivial (1.6–1.9 cm for subject 1, 0.7–0.9 cm for subject 2), this soft element motion was not enough to seriously impede the compression of the springs, although some compression was undoubtedly lost, particularly in the case of subject 1.

These kinematic disparities between brace and leg may have contributed to the weaker than expected performance of the damper system (Table 2). As the knee flexes, some of the resulting leg motion is absorbed by the compression of padding and soft tissue, causing the brace to lag slightly behind the leg in both angular position and angular velocity. During loading response this is particularly visible (Fig. 7). The brace is flexing at a lower rate than the knee, therefore the dampers connecting the top and bottom portions of the brace (refer to Figs. 1 and 3) are compressing more slowly than designed. Because damper force is proportional to velocity, a correspondingly lower force is generated. While the effects of this phenomenon are present in the data, the positive trend displayed by subject 2 (a reduction in required knee moment) indicates that this problem can be overcome.

The unexpected knee moments subject 1 displayed during the fully active trials (Table 2) are too extreme to attribute solely to the effects of the damper—the moment generated by the brace is in no way high enough to cause such significant differences opposite to what was predicted. Moreover, the changes from the control tests are present even in the ground reaction moments recorded by the force plate. That is to , say, despite controlling for gait speed and discarding any trials containing mis-steps onto the force plate, there appear to have been large corrections by the subject to maintain a natural-feeling gait. It is unknown why that tendency is exhibited by one subject and not the other—the only apparent difference between the two is one of brace fit and spring precompression.

As previously stated, a goal of the damper support system is to promote knee flexion during the loading response phase of gait. In OA patients this is pathologically reduced, leading to a stiff-legged gait. Because these tests were conducted using healthy subjects, this effect cannot be evaluated. We can, however, still examine the maximum knee flexion achieved at this point in stance (Table 4).

In both subjects' fully active tests we see these angles unchanged from the control trials. Interestingly, subject 1's inactive tests exhibit inhibited flexion during this phase of gait. It is encouraging to see that powering on the dampers appears to restore normal knee flexion angles.

4 Conclusions and Further Research

The goal of this study was to validate the underlying concept of the design by examining its performance in three principal tasks: reducing the load experienced at the knee joint during stance, generating a supportive moment about the knee, and interfering minimally with natural gait characteristics. Significant reductions in knee load were recorded for the majority of trials, however deformation of the underlying padding and tissue reduced the effect for at least one of the subjects. The predicted assistive moment was present but not statistically significant for one subject (once again likely due to substrate deformation), while for the other the system induced a change in gait such that the required knee moments were increased. Neither subject experienced a large change in knee angle during swing or stance, however subject 2 displayed a higher than ideal change immediately before heel-down.

The observed results suggest that the subsystems were operating as designed, but point to obvious factors that hindered the performance of the prototype brace. First, many of the inconsistencies observed throughout the trials can be attributed to or enhanced by poor ergonomic design of the prototype. An inefficient connection between brace and leg is thought to have caused excessive soft tissue and padding deformation, and ease-of-use issues are likely to have resulted in subject 2's extra spring precompression or incorrect mechanism position. The design of a more stable system to attach brace to leg will be a necessary step before proceeding with further investigations. Second, the consistency and magnitude of the damper effect could be enhanced by further optimization, of both control circuit design (to refine the system now that in vivo sensor signals have been recorded) and damper placement (for a more effective moment arm and load path).

As with any novel orthosis or prosthesis, the ergonomic impact of the design will need to be quantified, a question whose answer the design requirements of this investigation were unable to facilitate. In particular, the hypothesized reduction in brace-leg slippage due to a more accurately aligned hinge mechanism will need to be tested, as well as the perceived effect on patient comfort resulting from the redistribution of forces around the knee.

Taken as a whole, this study validates the core design concepts behind the brace. Adjustments to controls, layout, and ergonomics will be required, but the fundamental logic governing the design is sound. Once the specific design and fabrication changes mentioned above have been implemented, the data collected in this study supports further investigation into the brace's clinical effectiveness in treating pathological patients. This design concept could open avenues for patient-specific, customizable braces that are more capable of effectively treating a larger range of knee OA patients.

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