Design Evaluation of a Novel Multicompartment Unloader Knee Brace

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Knee osteoarthritis (OA) is a significant problem in the aging population, causing pain, impaired mobility, and decreased quality of life. Conservative treatment methods are necessary to reduce rapidly increasing rates of knee joint surgery. Recommended strategies include weight loss and knee bracing to unload knee joint forces. Although weight loss can be beneficial for joint unloading, knee OA patients often find it difficult to lose weight or begin exercise due to knee pain, and not all patients are overweight. Unicompartment offloader knee braces can redistribute joint forces away from one tibiofemoral (TF) compartment; however, <5% of patients have unicompartmental tibiofemoral osteoarthritis (TFOA), while patients with isolated patellofemoral or multicompartmental OA are much more common. By absorbing body weight (BW) and assisting the knee extension moment using a spring-loaded hinge, sufficiently powerful knee-extension-assist (KEA) braces could be useful for unloading the whole knee. This paper (1) describes the design of a spring-loaded tricompartment unloader (TCU) knee brace intended to provide unloading in all three compartments of the knee while weight-bearing, (2) measures and compares the force output of the TCU against the only published and commercially available KEA brace, and (3) calculates the static unloading capacity of each device. The TCU and KEA braces delivered maximum assistive moments equivalent to reducing BW by approximately 45 and 6 lbs, respectively. The paper concludes that sufficiently powerful spring-loaded knee braces show promise in a new class of multicompartment unloader knee orthoses, capable of providing a clinically meaningful unloading effect across all three knee compartments.
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Introduction

Knee osteoarthritis (OA) is a chronic joint disease estimated to affect between one-third [1] and almost one-half (45%) of the elderly population [2]. Knee OA is generally characterized by loss of joint cartilage, as well as changes to the articulating bones, ligaments, synovial membrane, and joint capsule [3]. The disease is commonly linked to chronic joint pain, a loss of functional independence, and a decrease in quality of life. The associated pain and disability often varies with disease severity and the distribution of OA across different compartments of the knee [4–6].

Osteoarthritis can occur within three different compartments of the knee: the medial and lateral tibiofemoral (TF) joints, or the patellofemoral (PF) joint [7–9]. Among symptomatic knee OA patients, evidence of OA is usually observed in two or all three compartments of the knee [4,5], and patellofemoral osteoarthritis (PFOA) is more commonly observed than tibiofemoral osteoarthritis (TFOA) [6]. For example, in a group of 259 candidates for knee replacement surgery, 59% had tricompartment OA, 28% had bicompartment OA, and 4% had unicompartment OA [4]. In a study looking at radiographs of 777 adult patients with knee pain, 40% had combined TFOA and PFOA, 24% had unicompartment PFOA, and 4% had unicompartment TFOA [5]. While the prevalence and significance of PFOA were largely overlooked for many years [7], recently, awareness of the importance of PFOA is increasing in both clinical practice and research [10]. Individuals with PFOA often experience pain that increases when the knee is flexed and bearing weight and may experience higher levels of disability than those with TFOA [11]; furthermore, relatively fewer conservative treatments (e.g., bracing, taping, exercise, or manual therapy) have proven effective for PFOA versus TFOA [7,12,13].

Given the heterogeneity in the clinical presentation of knee OA with respect to severity, symptomatology, and radiographic distribution within the knee [4,6,9,11], current clinical guidelines recommend individualized treatment and prevention strategies with a combination of noninvasive and nonpharmacological strategies in the first-line management of knee OA. An overarching theme with near universal consensus across these guidelines is to provide strategies that unload the damaged joint, which may reverse structural damage to the joint, delaying or eliminating the need for invasive therapies [2,3,8,14,15]. Suggested strategies for unloading the knee include body weight (BW) reduction, changes in lifestyle, exercise, pacing of activities, and using walking aids or knee braces [2,3,8,14,15].

Among overweight (body mass index [BMI] $\geq$ 25) and obese (BMI $\geq$ 30) patients, the most common method recommended for unloading the joint is through weight reduction [3]. Weight loss of just 11.2 lbs (approximate 5% weight reduction for average overweight/obese knee OA patients [16,17]) has been shown to decrease the risk of knee OA by as much as 50% [18]. The marked impact of small body weight reductions on the risk of developing knee OA is thought to be the result of a disproportionate relationship between body weight and knee joint loading where a 1 lb decrease in body mass has been shown to provide a fourfold decrease in internal knee forces during walking [19]. While small reductions in body weight can dramatically reduce the lifetime risk of knee OA, previous research has demonstrated that a 10–20% weight reduction among overweight or obese knee OA patients is required to achieve clinically meaningful improvements in pain, function, health-related quality of life, and knee joint loading outcomes [16,17,19,20]. Notably, however, overweight or obese individuals who lose $\geq$20% of their starting body weight experience the largest clinically relevant benefits [16]. While weight loss can be an effective means for alleviating the symptoms of knee OA, many patients find it difficult to lose weight [21], while others find it difficult to begin exercising due to knee pain, leading to a cycle of further weight gain and increasing joint pain [22].

Another common method for unloading the knee joint is through knee bracing. Most knee OA braces attempt to restore

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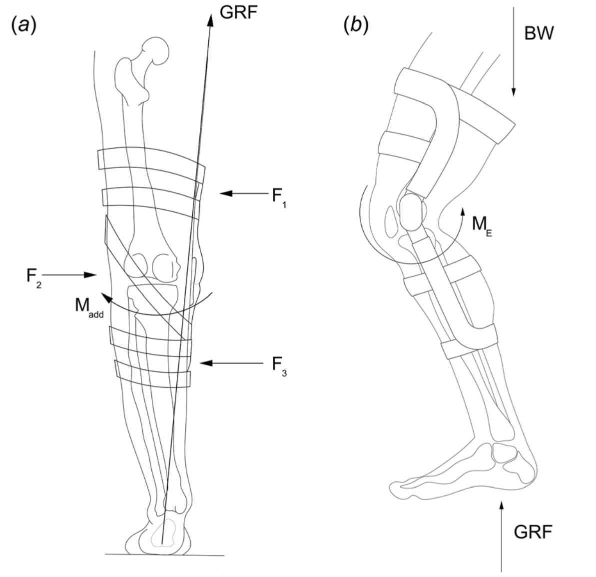

Fig. 1 Free body diagrams of (*a*) a typical unicompartment TFOA offloader brace, adapted from Gross and Hillstrom [28] and (*b*) the TCU brace described in this paper. GRF is the ground reaction force, BW is the body weight force, F_1, F_2, and F_3 are the forces exerted on the leg by the TFOA offloader brace, M_{add} is the corrective adduction moment generated by the unicompartment TFOA offloader, and M_E is the external moment generated by the TCU. (*a*) In unicompartmental TFOA, the GRF creates an adduction moment acting about the knee due to malalignment of the tibia and femur. A typical unicompartment TFOA offloader acts by applying F_1, F_2, and F_3 to the leg using a three-point bending mechanism to generate M_{add} in the frontal plane and realign the tibia and femur. (*b*) The TCU acts to extend the knee (assist the quadriceps muscles) and unload the knee joint. M_E is generated by the brace in the sagittal plane and assists the quadriceps to straighten the leg against the GRF and BW forces.

function and reduce pain in patients with unicompartmental OA of the TF joint [23–27]. Unicompartmental TFOA typically results from malalignment of the tibia and femur in the frontal plane, turning a portion of the ground reaction force into an adduction moment acting about the joint [28,29]. By applying an external moment (or "corrective force") to one side of the knee, unicompartment offloader braces aim to support the knee in a more upright position, reducing the adduction moment and redistributing (or "offloading") joint contact forces from the affected to the unaffected TF compartment[2] (Fig. 1(*a*)) [28]. Unicompartment offloader braces are a cost-effective treatment method that can decrease pain, joint stiffness, and drug dosage, while increasing quality of life [30–34]. Unfortunately, because a low percentage (4%) of patients have unicompartmental TFOA [4], traditional unloader braces are not indicated for most patients with knee OA who are likely to have patellofemoral or multicompartmental disease [4,5].

To our knowledge, no existing braces attempt to provide unloading for multicompartmental knee OA. Braces for PFOA are relatively uncommon and typically act by realigning the patella, thereby increasing joint contact area in order to reduce pressure [28]. However, limited evidence exists in support of their efficacy [13,35] and while patellar realignment could be useful in certain cases [12,36], existing PFOA braces are not intended to unload a correctly aligned PF joint during weight bearing knee flexion when the symptoms of PFOA are most aggravated [6–8].

A new brace design incorporates a spring-loaded hinge to provide passively powered knee extension assistance during the swing phase of gait. These knee-extension-assist (KEA) devices work by capturing the potential energy generated during knee flexion (e.g., in elastic-based springs) and then by applying a moment to the leg to assist the knee into extension [37–43]. While several devices exist [37–43], only one has been published on and commercialized [37–39]. The OA Rehabilitator™ (Guardian Brace, Pinellas Park, FL; "KEA") incorporates condylar TF offloading and a spring-loaded hinge to assist the function of the quadriceps muscles and help the lower leg come forward during the swing phase of gait [37–39]. In doing so, the KEA can help OA patients with quadriceps weakness regain mobility and increase walking-based exercise. While KEA devices certainly show promise for unicompartmental TFOA [37–39], they were not designed to unload mechanical joint forces while weight-bearing or in more than one compartment of the knee [37–43]. Accordingly, similar to unicompartment offloaders, commercially available KEA braces are not indicated for individuals with patellofemoral or multicompartmental knee OA [37–41], and the population of patients who can benefit from KEA bracing may be limited.

Existing commercially available KEA devices were not designed to assist knee joint extension while weight-bearing and are thus unlikely to reduce TF or PF joint loading [37–41]. However, unloading joint forces from all three knee compartments is theoretically possible while weight-bearing if an assistive force is applied to the back of the leg that is sufficient to reduce the magnitude of the internally generated moment required for knee joint extension. This paper describes the design of a powerful spring-loaded knee brace (the Levitation® Tri-Compartment Unloader™, Spring Loaded Technology, Halifax, NS) that is intended to assist quadriceps function while providing a clinically meaningful tricompartment unloading effect in the knee (i.e., equivalent to what would be achieved by a $\geq$20% reduction of body weight; Fig. 1(*b*)). After describing the design and function of the tricompartment unloader (TCU), the assistive moment of the brace is mechanically tested and compared with the KEA brace described above. Finally, the theoretical unloading moment provided by each brace is calculated and compared in terms of the effective body weight reduction offered by each brace.

Methods

Brace Design. This paper outlines the design of a novel knee brace recently commercialized by Spring Loaded Technology Inc. (the Levitation® Tri-Compartment Unloader™) that is intended to provide tricompartment unloading [44]. The TCU brace consists of an upper frame that attaches to the thigh, and a lower frame that attaches to the calf. Both the upper and lower frames are constructed from a rigid carbon reinforced composite material and lined with soft fabric/foam padding for comfort (Fig. 2). The upper frame is held in place above the knee with flexible straps, proximally around the posterior upper thigh and distally around the anterior lower thigh just above the knee (strap numbers 1 and 2 in Fig. 2). The lower frame is held in place below the knee with two straps: the first wraps the full circumference of the proximal calf while the second is attached distally and anteriorly to wrap around the shin (strap numbers 3 and 4 in Fig. 2). The upper and lower frames are connected by a pair of polycentric hinges on the lateral and medial sides. The lateral hinge houses the brace power components (i.e., the spring-loaded hinge, described below). The medial hinge is unpowered and provides motion synchronization during flexion and extension using gear teeth.

The brace assists knee extension by using springs to tension a strong, flexible cord that passes over a cam to rotate the lower

[2]Knee braces intended to treat unicompartmental knee OA are interchangeably referred to as unicompartment "unloaders" and unicompartment "offloaders" in the literature. Given the mechanism of action for traditional unicompartmental knee OA braces, involving a redistribution of forces from one side of the knee to the other, we believe the term "offloader" is most appropriate, while the term "unloader" should be reserved for devices that attempt to *reduce* rather than *redistribute* the total force placed on the joint.

Fig. 2 Schematic diagram of the TCU brace. Components include straps 1–4, powered and unpowered hinge, and upper and lower carbon-fiber shells.

portion of the brace relative to the upper. The extension assist moment is transferred to the leg by straps 1 and 2 on the upper frame and direct pressure of the lower frame on the back of the calf. Straps 1 and 2 on the upper frame couple it to the upper leg, while the extension assisting moment rotates the padded lower frame, pressing on the back of the leg approximately eight in. below the knee. Strap 3 prevents the brace from sliding down the leg but does not transfer any anterior–posterior forces to the leg.

Spring Design. The spring is the novel, powerful mechanism behind the TCU knee brace [45]. Each cylinder within the liquid spring was designed to provide an initial force output of 250 lbf at 1 in. of deflection and maintain at least 80% of this initial force after undergoing 100,000 *full* compression cycles. The spring develops force when its piston rod is forced into a sealed chamber filled with compressible fluid. As the piston is forced into the sealed chamber, pressure rapidly accumulates within the cylinder. Therefore, full compression cycles of the spring (which would only occur in the brace during a deep squat) were expected to exert maximum wear and tear. A proprietary liquid spring was designed after all traditional springs and available liquid springs failed to meet the requirements of the project, including being lightweight, compact, small enough to fit into a traditional knee brace envelope and reliable for sustained usage (Table 1).

Hinge Design. The powered (lateral) hinge is the mechanism that houses the springs and allows the brace to provide the assistive knee extension moment [46]. A bridge connects the ends of the two spring piston rods to a cord, so the tension in the cord creates compression in the springs which stores potential energy (Fig. 3). The distal end of the cord is fixed to the lower frame after passing over a variable radius cam, which converts the cord tension into a moment that rotates the lower frame to assist extension. The shape of the cam is designed to vary the moment as the angle between the upper and lower leg changes. The hinge allows for a maximum range of motion of 0–120 deg (flexion) while wearing the brace.

Adjustability of the Assistive Moment. The extension assistance provided would require sufficient hamstring strength to overcome the external moment provided by the brace and achieve knee flexion. To address this, the moment versus flexion behavior of the brace was designed to be modified via an adjustment system, consisting of a cord adjustment, "power knob," and interchangeable cam profiles (see hinge design). The cord length can be adjusted at the bridge connection to the springs. This can create either preload if tightened, or a "dead zone" (where no moment is generated until the brace is flexed to a minimum angle) if loosened. The cord can also be adjusted by a power knob on the side of the brace to turn it into "high power mode" where the cord is tightened to increase the load, or "low power mode" where the cord is loosened and effectively acts as a disengage function to allow free motion up to approximately 80 deg of knee flexion. The power knob can be used to dramatically reduce the assistive force provided by the brace, including when it is not wanted (e.g., while seated for an extended period).

Table 1 Design intent versus current state of the springs

	Design intent	Current state
Spring cross section	Maximum 0.5 in. × 1.625 in.	0.5 in. × 1.4 in.
Spring length	Maximum 6 in.	6 in.
Spring constant	Minimum 500 lbf/in.	460–510 lbf/in.
Stroke length	Minimum 1 in.	1.23 in.
Cycles to failure	Minimum 100,000 cycles	100,000—190,000 cycles
Failure mode	Passive, gradual failure	Slow failure by microleaking of the working fluid. No sudden power loss.
Corrosion resistance	Corrosion resistant	Stainless steel and bronze used. Corrosion resistant as confirmed by field usage.

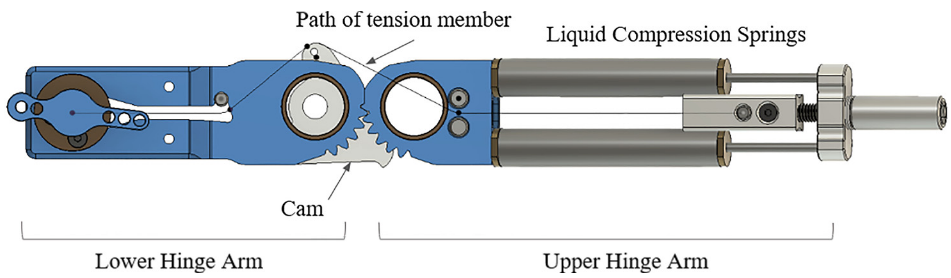

Fig. 3 Side view of the hinge mechanism. Components include lower hinge arm, tension member, cam, upper hinge arm, and liquid compression springs.

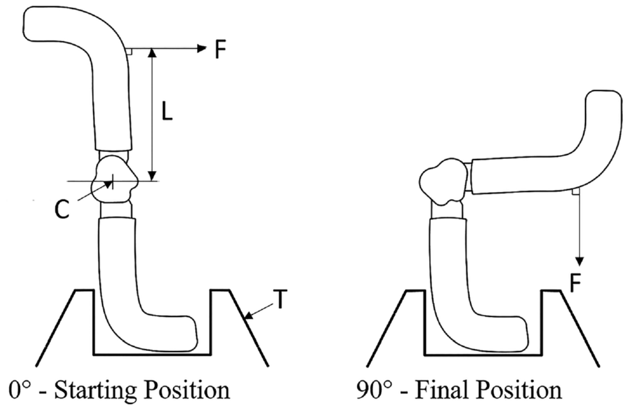

Fig. 4 Testing setup for brace force testing. *F* is the force applied perpendicular to the frame. *L* is the length from the center of rotation to the force line of action. *C* is the center of rotation. *T* is the table to which the lower brace portion is fixed.

In addition to the adjustability offered by the power knob, the shape of the cam can be altered to tailor the force response profile of the brace and to provide a reduced assistive moment in relatively shallow degrees of knee flexion (e.g., similar to KEA while walking) and increased assistance in deeper degrees of knee flexion. The combination of the cord adjustment, power knob, and cam allows the brace to apply different assistive profiles for different therapeutic purposes, different body weights, or users with varying levels of strength.

Comparative Brace. Brace force output versus flexion angle was tested for the TCU brace and compared to the only other published and commercially available KEA brace to determine the potential unloading effect of each device. The KEA (OA Rehabilitator^{TM}, Guardian Brace, Pinellas Park, FL) is a knee brace equipped with a pneumatic air bladder system (intended to provide unicompartment offloading), and an elastic cord embedded in the polycentric hinge to provide KEA functionality [37]. The maximum range of motion for the KEA is 0–105 deg. The KEA was equipped with an elastic tension cord at each hinge, rated as 5 lbf by the manufacturer.

Brace Force Testing. To test the extension assistance offered by each device, the force output of each device was measured at 0 deg, 30 deg, 60 deg, and 90 deg flexion angles. During these tests, the lower arm of each brace was clamped in an upright position to a workbench (Fig. 4). A digital load scale (Maple Leaf Travel Accessories, Oakville, ON) was attached to the upper hinge arm at the distance specified by the lever arm. The scale had a rated resolution of 0.02 lbs and accuracy of ±0.3 lbs. At each measurement angle, the scale was oriented such that the force was perpendicular to the upper lever arm. All force measurements were repeated five times for each flexion angle, and the final force output is the average of all trials.

The lever arm was measured using a steel ruler. The lever arm measurements were 8.0 in. for the TCU brace and 4.1 in. for the KEA brace. The TCU brace cord adjustment system was set to factory settings for force testing, so the spring started to engage as soon as it started to bend. The TCU cam used for testing was designed to maximize energy transfer from the springs to the assistive moment of the brace.

Results

Both the TCU and KEA provided an assistive moment at 90 deg knee flexion. The TCU brace generated a greater assistive moment at 90 deg, rising from 12.3 in.-lbs at 0 deg to 181.0 in.-lbs at 90 deg flexion, an increase of 168.7 in.-lbs (Fig. 5). The KEA brace provided no assistive moment at 0 deg flexion and 22 in.-lbs at 90 deg flexion. Notably, the KEA exhibited a slightly decreased assistive capacity between 60 deg and 90 deg, so the peak knee extension assistance occurred at a flexion angle of less than 90 deg.

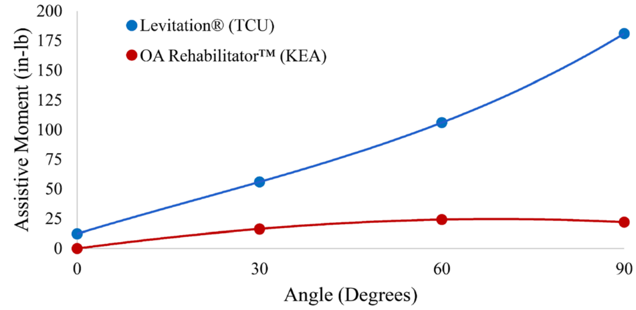

Fig. 5 Brace assistive moment output profiles across flexion range of motion. Lines of best fit ($R^2 = 1$) are presented for each brace profile.

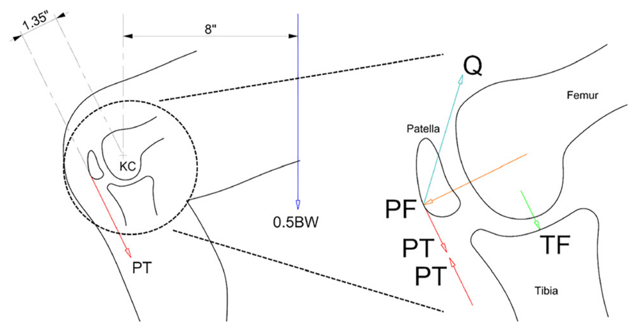

Fig. 6 Knee model used for theoretical joint contact force calculations, based on Masouros et al. [47]. KC is the knee joint center. PT is the patellar tendon force. PF is the patellofemoral contact force. *Q* is the quadriceps force. TF is the TF contact force.

Theoretical Unloading Provided by the Brace. Calculations of theoretical knee joint contact force reduction provided by each device are based on a model by Masouros et al. [47]. In this model, it was assumed that BW is distributed equally across both feet, so each foot carries 0.5 BW (Fig. 6).

Assume a case where an individual is rising from a chair[3]. At the time contact with the chair ends, the knee is flexed to approximately 90 deg. A static analysis of the moments about the knee joint center (ΣMKC) in the sagittal plane gives the patellar tendon force (PT) as follows (see also Fig. 6):

$$\begin{aligned} \Sigma \text{MKC} &= 0 \\ 0 &= 1.35\,\text{in.}\,\text{PT} - 8\,\text{in.}\,(0.5\text{BW}) \\ \text{PT} &\approx 3\text{BW} \end{aligned} \tag{1}$$

From this knee model, knee joint forces are directly proportional to each other. The model states that PT $\approx 0.7Q$ and uses tip-to-tail vector summing to derive the relationships between different knee forces as follows [47]:

$$\text{PF} \approx 5\text{BW} \quad \text{TF} \approx 3.5\text{BW} \tag{2}$$

[3]In terms of knee-flexed weight-bearing movement, this activity is both common and reasonably representative of those that aggravate PFOA, e.g., going up or down stairs, standing from seated, crouching or squatting, kneeling, getting into or out of the bath, and getting into or out of the car [6–8], where knee flexion angles typically range from 78 deg to 131 deg [60].

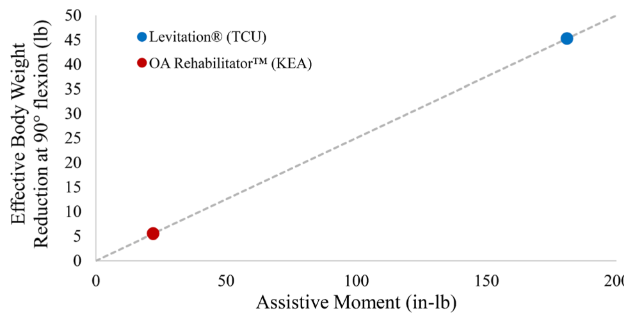

Fig. 7 Effective body weight reduction at 90 deg flexion versus assistive external knee moment for both knee braces

When stated in terms of PT, the relationships are the following:

$$Q \approx 1.43\text{PT} \quad \text{PF} \approx 1.83\text{PT} \quad \text{TF} \approx 1.17\text{PT} \tag{3}$$

As the relationships between different internal knee forces are directly proportional to one another, any force reduction in PT propagates proportionally to any other force (i.e., Q, PF, and TF).

Theoretical Comparison to the Knee-Extension-Assist. Each brace provides an assistive, external moment (M_E) to the KC. From Eq. (1), the assisted patellar tendon force (PT′) is calculated as follows:

$$\begin{aligned} &\Sigma \text{MKC} = 0 \\ &0 = 1.35\,\text{in.}\,(\text{PT}') + M_E - 8\,\text{in.}\,(0.5\text{BW}) \\ &\text{PT}' = 3\left(\text{BW} - \frac{M_E}{4\,\text{in.}}\right) \end{aligned} \tag{4}$$

Based on the brace force testing (Fig. 4), PT′ using the TCU can be calculated as follows:

$$\begin{aligned} &\text{PT}' = 3\left(\text{BW} - \frac{181\,\text{in.}\cdot\text{lbf}}{4\,\text{in.}}\right) \\ &\text{PT}' = 3\,(\text{BW} - 45.3\,\text{lbf}) \end{aligned} \tag{5}$$

This shows that the assisted patellar tendon force at 90 deg knee flexion when using the TCU is the equivalent of reducing body weight by up to 45.3 lbf (Fig. 7). For the KEA brace, the effective reduction in body weight was calculated to be 5.5 lbf at 90 deg of knee flexion. The total unloading effect provided by the TCU and KEA across each compartment of the knee is shown in Table 2 for an average overweight patient with knee OA [16,17].

Discussion

This paper describes the design of a novel TCU knee brace (the Levitation® Tri-Compartment Unloader™) intended to provide tricompartment unloading by applying an assistive moment to the back of the leg. Using a theoretical model of the knee [47], calculations demonstrated that the TCU brace could reduce joint contact forces to a level that would be achieved by a reduction of up to 45 lbs in body weight. By comparing the TCU to a commercially available KEA (the OA Rehabilitator™), we further demonstrated that the level of joint unloading achieved is proportional to the assistive moment offered (Fig. 7).

Unloading Provided by the Tricompartment Unloader Brace. To provide a clinically relevant unloading effect through weight loss, a reduction of at least 10–20% of body weight is required [16]. Calculations of theoretical joint force reductions showed that the TCU could provide a sufficiently powerful assistive moment to unload the knee equivalent to reducing body weight by 22% in a 205 lbs individual [16,17]. By contrast, in the same 205 lbs individual, the KEA could provide a 2.7% effective body weight reduction. While 205 lbs represents the average weight in a sample of overweight to obese knee OA patients selected based on BMI for a weight-loss intervention [16,17], the weight of an individual with knee OA from the general population may be lower. Previous studies report an average weight of approximately 165 lbs among knee OA patients, who are still (on average) classified as overweight based on BMI [48–52]. Based on an average weight of 165 lbs, the force output of the TCU brace would provide unloading equivalent to a 27% body weight reduction while the KEA would provide unloading equivalent to a 3.3% body weight reduction (Table 3).

Table 2 Tricompartmental unloading offered by both braces for an individual with 205 lbs body weight, according to Eqs. (3) and (5)

		Assisted with TCU brace		Assisted with KEA brace	
Location of force within joint	Unassisted force (lbf)	Force (lbf)	Force reduction (compared to unassisted) (lbf)	Force (lbf)	Force reduction (compared to unassisted) (lbf)
PT	615.0	479.1	135.9	598.5	16.5
Q	879.5	685.1	194.4	855.9	23.6
PF	1125.5	876.8	248.7	1095.3	30.2
TF	719.6	560.5	159.1	700.2	19.4

Note: TCU is the tricompartment unloader, KEA is the knee extension assist, PT is the patellar tendon force, Q is the quadriceps tendon force, PF is the patellofemoral contact force, and TF is the tibiofemoral contact force.

Table 3 Absolute and relative body weight reduction provided by both braces for two groups of knee osteoarthritis patients

	Reduction in body weight (lbs)	Percentage BW reduction for a 205 lbs individual (%)	Percentage BW reduction for a 165 lbs individual (%)
TCU	45.3	22.07	27.42
KEA	5.5	2.68	3.33

Note: TCU is the tricompartment unloader, KEA is the knee extension assist, and BW is the body weight.

Differentiation of the Tricompartment Unloader Brace by Design. It is important to note that, to our knowledge, commercially available KEA braces were not originally intended to provide tri-compartment unloading benefits while weight bearing [37–41]. Rather, KEA braces are generally used as a tool to help patients with weak quadriceps extend their knee during the swing phase of gait, thereby promoting increased walking-based exercise [37–41]. Nonetheless, the present paper demonstrates that sufficiently powerful extension assistance may be used to provide tri-compartment unloading benefits when the knee is flexed and bearing weight. Given that unloading the knee is commonly associated with a reduction in pain for patients with knee OA [15,53], the TCU brace may allow for increased pain-free mobility in a wider range of activities of daily living, namely those including weight-bearing knee flexion. Similar to the concept behind the KEA, by encouraging pain-free mobility, individuals using the TCU brace may become (or remain) more active, thus naturally building strength. As brace users increase activity and start to rebuild strength, the TCU brace allows them (or their doctors) to reduce the assistive moment provided using the cord adjustment mechanism (see brace design). This cord-adjustment feature could help promote muscular strengthening/rehabilitation and may be used in some patients to prevent long-term reliance on the brace.

Other unloading braces are typically focused on providing unicompartmental offloading of the TF joint [23–27,32–34] without addressing PF compartment loading. An important limitation of unicompartment offloaders is that as the offloading benefit is realized by one side of the TF joint, the opposite TF compartment experiences an increase in loading. As little as 5 deg varus/valgus malalignment can increase compressive loading in the TF compartment by up to 90% [29], so this redistribution of contact forces could increase the likelihood of the patient developing bicompartmental OA [28]. Similarly, braces designed to target the PF compartment do not address TF joint loading [35] and do not consistently provide clinical benefits [13]. However, the current analysis suggests the unloading benefits of the TCU brace may be experienced by all three knee joint compartments.

A distinct benefit of the TCU is that it could be used to help unload the PF joint [4,5,6,9,10,11]. There are relatively fewer conservative treatment options for PFOA compared to TFOA, and while existing strategies attempt to re-align the patella, their clinical efficacy remains uncertain [7,12,13]. It is well established that PF joint contact forces increase with increasing flexion angles while weight bearing [53,54], and that patients with PFOA experience increased pain with deeper levels of knee flexion [7,53]. Unloading the joint is widely recommended for reducing pain [15,55], and the current analysis suggests that the TCU will provide unloading within all knee compartments (Table 2). As a result, the current TCU may be an effective treatment option to reduce pain and functional limitations in patients with PFOA.

Clinical Benefits of Multicompartment Unloaders. Unloading all three knee joint compartments may afford patients' many benefits. For example, consistent with clinical guidelines which encourage joint unloading for knee OA [2,3,8,14], the short-term effects of unloading include pain and symptom relief during weight-bearing knee flexion. The long-term effects may be greater; for example, the reduction in joint contact forces via weight loss, wedged insoles, unicompartment offloader braces, or high tibial osteotomy has been shown to reduce structural damage and improve tissue remodeling, increasing the potential of the joint to restore normal function [15]. A brace that is capable of unloading the knee joint may allow for improved soft-tissue repair [56], or be used as a rehabilitation tool to help improve strength and range of motion while weight-bearing. Rehabilitation protocols highlight the need for progressive weight bearing, passive extension, quadriceps control and neuromuscular training following knee procedures including meniscal repair [57], anterior cruciate ligament reconstruction [58], and articular cartilage repair [59–64], all of which may be aided by the TCU's powerful and adjustable knee extension assist mechanism.

Limitations and Future Directions. To estimate internal knee joint forces and to help qualify the TCU brace design, the theoretical model from Masouros et al. [47] was used, which outlines the loading and articular mechanics of the joint. This model is limited to estimating static internal knee joint forces when a specified set of geometrical, anatomical, and structural parameters are used, but is nonetheless considered a useful model for preliminary analyses such as those contained in the current paper.[4] Future modeling and biomechanical studies should aim to determine internal joint forces across the full range of motion of the knee, including when small variances to joint anatomy are possible.

While the results of this study show promise for TCU knee braces, additional research is required. Previous research on KEA bracing has shown improvements in strength measures, functional fitness, gait parameters, and patient reported outcomes after 3-months of use [37–39]. Similar studies are required to evaluate the clinical, functional, and economic benefits that the TCU may offer as a conservative treatment for patients with multicompartment or patellofemoral knee OA.

Conclusions

A powerful TCU brace was evaluated, and calculations indicated that the brace would provide tricompartment unloading within the knee, equivalent to reducing body weight by up to 45 lbs. Both the TCU and KEA braces provided unloading of the knee proportional to the assistive moment generated by each brace. However, only the TCU brace offered a tri-compartment unloading effect that is likely to be clinically relevant [16,17,19]. The TCU brace shows promise for a new class of multicompartment unloader knee braces, capable of serving a wider range of patients with knee OA.

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Nomenclature

BW = body weight
KC = knee joint center
KEA = knee extension assist
M_E = external moment
PF = patellofemoral
PT = patellar tendon force
PT′ = assisted patellar tendon force

[4]The Masourous model has been used in other studies as a basis to examine the TF joint pathomorphology in knee OA [61], gender-specific bilateral gait symmetry [62], and to evaluate an instrumented rehabilitation device [63]. Notably, the forces within the PF and TF joints at 90 deg (5 BW and 3.5 BW, respectively) from this model [47] agree with previous empirical research stating that PF ranges from 3BW [54] to 7.6BW [53], and TF from 3BW [54] to 3.7BW [64] during high flexion (i.e., 90–140 deg) activities.

$Q =$ Quadriceps force
TCU = tricompartment unloader
TF = tibiofemoral
ΣMKC = sum of moments about the knee joint center

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