A novel method to analyze the mechanics of unloader braces for medial knee osteoarthritis

*A two brace comparison*

By

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Abstract

Bracing is a treatment option for medial knee osteoarthritis that reduces compressive forces in the medial knee through the application of an external brace moment. In theory, this moment reduces the external knee adduction moment, whose magnitude has been related to the severity of osteoarthritis (Miyazaki et al., 2002). Studies have quantified the brace moment to determine whether it could significantly reduce joint loads (Pollo et al., 2002; Self et al., 2000; Schmalz et al., 2010), however none have considered the pressure distributions between the brace and the user, which can be used to evaluate the impact of specific design components on the brace moment. Therefore, the purpose of this study was to provide a novel method of analyzing brace mechanics using pressure measurements between the brace and the user. The experimental setup consisted of a motion capture system, an instrumented treadmill, two pressure mats, and two load cells. This setup was used to quantify important aspects of brace mechanics, specifically, the thigh lever arm, the force applied to the lateral knee, the brace deflection, the brace moment, and the brace stiffness. Two braces were tested, being a single-hinged brace and a dual-hinged brace, on five subjects, who performed two thirty second walking trials on the instrumented treadmill. The results showed that there was some variability as a percentage of stance phase, however, brace mechanics were consistent through mid-stance. Therefore the braces were compared at mid-stance using a paired t-test. This showed a larger lateral load (p < 0.01), brace deflection (p = 0.02) and brace moment (p < 0.01) for the dual-hinged brace, while the stiffness of the single-hinged brace was larger (p = 0.03). Furthermore, there were no observed differences in the thigh lever arm between the braces (p > 0.05). These differences were attributed to design features of the braces, the most important being the tightening mechanism, which we believe contributed to both the higher lateral load and the lower stiffness for the dual-hinged brace. Using these results and the pressure distributions, a new brace design was proposed, modifying brace features to increase brace effectiveness. Overall, the proposed method proved useful when comparing braces, and allowed for brace improvement, making it a reasonable non-invasive means of analyzing brace mechanics.
Co-Authorship

This thesis contains original work produced by Marcus Brown. Chapter 3 was presented in the format of a journal submission, to be submitted to the Journal of Biomedical Engineering under the co-authorship of Scott Brandon, Dr. Kevin Deluzio, and Dr. Scott Selbie.
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Chapter 1

Introduction

1.1 Background

Osteoarthritis is the most common form of arthritis, affecting more than 3 million Canadians (The Arthritis Society, 2014). This disease occurs when cartilage (the material in joints that separates bones) and the underlying bone, degrades, resulting in bony spurs and cysts within the joint (The Arthritis Society, 2014). Osteoarthritis can affect all joints, but occurs most commonly in the medial compartment of the knee (American College of Rheumatology, 2014). Patients with knee osteoarthritis experience varying symptoms depending on disease severity, from mild stiffness, to complete loss of mobility (American College of Rheumatology, 2014).

Treatment options for knee osteoarthritis vary depending on individual symptoms, but are typically designed to alleviate pain, slow disease progression, and improve joint function (Ringdahl & Pandit, 2011). For mild osteoarthritis, minimally invasive treatments are prescribed, such as weight loss and low impact exercise (Ringdahl & Pandit, 2011). Knee
braces and joint injections are considered when lifestyle changes alone provide insufficient relief (Ringdahl & Pandit, 2011). When the disease reaches an intolerable level in terms of pain or mobility, more invasive treatments are used, such as a total knee replacement. In this surgical procedure, the distal femur and proximal tibia are replaced with mechanical implants fabricated using engineering materials (Ringdahl & Pandit, 2011). Although significant relief is achieved through total knee replacement, the operation is extremely invasive, and the implants have a limited life span (Ringdahl & Pandit, 2011). Therefore, it is imperative to slow the progression of osteoarthritis to avoid invasive treatments.

Some treatments designed to slow the progression of osteoarthritis focus on joint load reductions (Pollo et al., 2012; Hochberg et al., 2007; Street et al., 2013), because excessive joint loading has been linked to pain and disease severity (Miyazaki et al., 2002). Direct measurement of the forces within a joint however is invasive; therefore external loads have been adopted instead as a measure for treatment efficacy. Of particular interest is the external knee adduction moment, as cross-sectional studies have linked disease severity to the magnitude of the external knee adduction moment (Miyazaki et al., 2002). This moment is important as it describes how the external loads are distributed through the knee.

Considering knee anatomy, the distal femur consists of two condyles, located on the medial and lateral sides of the knee. These condyles rest on meniscus cartilage attached to the proximal end of the shank. When the leg is loaded, forces are transferred through the joint cartilage to the lateral and medial femoral condyles. Ideally, these forces are distributed between the medial and lateral sides, to minimize the maximum stress on the cartilage (Figure 1.1, Left). In certain cases, the contact loads distributed between the medial and
lateral sides are imbalanced (Figure 1.1, Right), possibly leading to cartilage degradation in the compartment with larger loading. A recent study (Kutzner et al., 2013) showed that the magnitude of the external adduction moment during gait is correlated with the magnitude of the contact loads transferred through the medial compartment of the knee. Accordingly, reducing the external knee adduction moment has been adopted as a primary objective for several treatments options (Pollo et al., 2012; Street et al., 2013).

![Figure 1.1: Schematic of knee showing forces distributed between the lateral and medial femur condyles (\(\vec{F}_{LAT}\) and \(\vec{F}_{MED}\)), as well as the net force transferred through the knee (\(\vec{F}_{NET}\)). When the forces on the medial and lateral sides are equal (\(\vec{F}_{LAT} = \vec{F}_{MED}\)) there is no moment applied to the knee (Left), however when these forces are uneven (Right), the result is a moment about the knee (\(\vec{M}_{ADD}\)). (Alia Medical Media, 2014)]

Off-the-shelf unloader knee braces are a mechanical intervention that attach to the thigh and shank of the osteoarthritic leg, and are designed to reduce the external knee adduction...
moment. In theory, this is achieved through the application of an external abduction moment (brace moment), which has been modeled using the principle of three-point bending for the braces of interest to this study (DJO Global, Vista, California; Schmalz et al., 2010). The loads responsible for this moment are a result of three distinct brace components, being the thigh and shank sections as well as the lateral hinge. For the braces of interest to this study, the thigh and shank sections of the brace are manufactured using aluminum and compressive padding (DJO Global, Vista, California), and attach to the mid-thigh and mid-shank of users using Velcro straps. These sections apply medial and lateral distributed loads to the subject in the frontal plane (Figure 1.2, B), $\vec{F}_{T1}$, $\vec{F}_{T2}$, $\vec{F}_{S1}$, $\vec{F}_{S2}$, which result in two net loads applied in the lateral direction, to the shank (Figure 1.2, C), $\vec{F}_{SHANK}$ and thigh segments (Figure 1.2, C), $\vec{F}_{THIGH}$). The final component is the lateral hinge, which contacts the user on the lateral epicondyle, and connects the thigh and shank brace sections. The interaction of this hinge with the user results in a force applied in the medial direction to the lateral knee (Figure 1.2, C), $\vec{F}_{KNEE}$), which combined with the laterally directed forces applied to the thigh and shank (Figure 1.2, C), $\vec{F}_{THIGH}$ and $\vec{F}_{SHANK}$), causes the brace moment applied at the knee. This moment counteracts the external knee adduction moment, thereby transferring load away from the medial compartment.
Figure 1.2: Schematic of *in vivo* brace use, showing unbalance medial ($\vec{F}_{\text{MED}}$) and lateral ($\vec{F}_{\text{LAT}}$) loads in the knee (A), five distributed loads applied by the brace to the user (B), the equivalent point loads from these distributed loads as well as their positions relative to the knee (C), and the redistribution of the medial and lateral condylar loads ($C, \vec{F}_{\text{MED}}$ and $\vec{F}_{\text{LAT}}$) as a result of the three-point bending load applied to the knee.

Assuming the three-point bending model governs brace operation, the brace moment is sensitive to three factors: (1) the force applied to the lateral knee, (2) the distance between the force applied to the lateral knee and the thigh reaction force, (3) and the distance between the force applied to the lateral knee and the shank reaction force (Hibbeler, 2003) ($M_{\text{brace}} = \frac{\vec{F}_{\text{KNEE}} \times \vec{d}_T + \vec{d}_S}{\vec{d}_T + \vec{d}_S}$). The force applied to the lateral knee (Figure 1.2, C), $\vec{F}_{\text{KNEE}}$ linearly affects the brace moment, and is adjusted by turning screws on the lateral side of
the braces. The distances to the thigh (Figure 1.2, C), $\vec{d}_T$, and shank (Figure 1.2, C), $\vec{d}_S$, reaction forces (called the thigh and shank lever arms) are governed by the fit and design of the brace. Accordingly, for a given brace, increasing the brace moment is achieved by increasing the lateral force applied to the knee, as the lever arm distances cannot be controlled or adjusted by the user.

In addition to the application of an external abduction moment, unloader braces could have secondary impacts on muscle activations and gait kinematics (Ramsey et al., 2007), both of which can influence the loading in the knee (Pagani et al., 2013; Shull et al., 2013). As these secondary changes may occur simultaneously with the application of the brace moment, it is difficult to ascertain the individual contribution of each factor towards external knee adduction moment reduction, which is important as each can significantly influence brace design. For instance, if the unloading effect of bracing is due to changes in kinematics, gait retraining could achieve the same result (Fregly et al., 2009), without the use of a brace, which is more economical for the patient. Alternatively, if muscle activation dominates, more minimalistic designs could offer the same relief for patients, while being more comfortable. This is important to consider, as patients have a tendency to stop using these braces due to discomfort, with greater than 40% of users stopping use within one year (Brouwer et al., 2006). However, if the unloading effect is primarily caused by the brace moment, current designs are suitable. Therefore, in order to assess the appropriateness of unloader brace design, all factors contributing to the unloading effect of braces, being altered muscle activations, changes in gait kinematics, and the brace moment, must be
quantified. The scope of this thesis includes quantifying the brace moment, and explaining the mechanism of application in terms of brace components.

1.2 Literature review

Several techniques have been adopted to measure the effectiveness of unloader braces. These techniques include direct *in vivo* measurement of joint forces, changes in medial condylar separation, and measurements of the brace moment, either quantified directly or using approximations. This section provides an overview of these experiments, including a summary of key findings and limitations. Following this discussion, an alternative method is presented, specifically to address the limitations of these experiments.

1.2.1 Direct *in vivo* contact force measurements

*In vivo* measurements of joint contact forces have been used to examine the effect of bracing (Anderson *et al.*, 2003; Kutzner *et al.*, 2011). Anderson *et al.* (2003) instrumented the medial compartment of osteoarthritic knees with a pressure transducer, and measured joint loads during double and single-leg stance for a single brace. No force reductions were observed between the braced and non-braced conditions, which were attributed to significant variability in the data. As the transducer only covered a portion of the medial compartment, small changes in knee alignment altered the contact area of the sensor, resulting in inconsistent measurements. Kutzner *et al.* (2011) instrumented the medial compartment of patients who had total knee replacement surgery (Figure 1.3), and measured contact forces for three subjects, comparing two brace designs. This experiment examined braced and non-braced conditions for walking as well as stair ascending and descending. The results showed decreases in medial loads, however the decrease was
variable, ranging between 7% and 30% at mid-stance between the two brace designs.

There are both advantages and disadvantages of using this technique (direct measurement) to quantify the unloading effect of bracing. One advantage is that joint contact forces are measured directly, which is not the case when using other parameters,
such as the external knee adduction moment. As there is inherent uncertainty when estimating the correlation between alternative parameters, such as the external knee adduction moment, and joint loads, direct measurements could provide more concrete evidence relating bracing to changes in joint contact forces. However, the protocol is experimentally challenging, making it difficult to collect accurate measurements (Anderson et al., 2003). Furthermore, instrumenting the medial compartment of knees is invasive; therefore, achieving a sample size sufficiently large to discerned differences between brace designs is difficult (Anderson et al., 2003; Kutzner et al., 2011). Finally, surgical intervention, which is required to measure joint contact forces, alters the joint environment. Therefore, although this technique results in direct joint load measurements, it does not reflect native loading in the knee, making the use of alternative parameters more suitable.

1.2.2 Medial condylar separation

One alternative to direct measurement of joint contact forces present in literature is the use of medial condylar separation, quantified using dynamic and static x-rays. This parameter has been adopted as it provides an indication of knee alignment changes as a result of bracing (Figure 1.4). Knee alignment is important as genu varum (bow-leggedness) has been associated with higher external knee adduction moments (Barrios et al., 2010), and a significant risk factor in the progression of medial compartment osteoarthritis (Birmingham et al., 2001; Sharma et al., 2011). Therefore, increases in medial condylar separation could decrease varus knee alignment, reduce the external knee adduction moment (Barrios et al., 2010), and possibly slow the progression of
osteoarthritis. The first study compared 5 brace designs during walking (Nadaud et al., 2005), which showed increased separation of 1-2 mm depending on the subject and the brace. Komistek et al. (1999) performed a similar experiment, however only using 1 brace, and measured average differences in condylar separation of 1.2 mm at heel strike, between the braced and non-braced conditions. Dennis et al. (2006) showed significant differences for 78% of participants; with an increased mean separation of 1.7 mm. Studies using static radiographs showed similar outcomes to these dynamic studies, with increased mean separations of 1.3-1.4 mm (Draganich et al., 2006; Matsuno et al., 1997). However, one study (Horlick et al., 1993) reported no significant changes between braced and non-braced conditions, during weight bearing and non-weight bearing. An important consideration when discussing these results is the accuracy of x-ray technology (whether static or dynamic), which has an approximate error of +/- 1 mm (Acker et al., 2011) when measuring condylar separation. The conflicting evidence in literature, as well as the magnitude of results compared to the accuracy of the measurement system, makes it difficult to determine whether increased medial condylar separation is achieved through bracing, revealing a limitation of this measurement technique.
Figure 1.4: X-ray fitting process used to measure medial condylar separation as a result of bracing, showing non-braced condition (Left), and braced condition (Right), with increased medial separation present in the braced condition (Right) (Dennis et al., 2006)

1.2.3 Brace moment

Other studies have used the brace moment, either measured directly, or using approximations, as a means of quantifying the effects of bracing. This parameter has been studied due to the relationship between the magnitude the external knee adduction moment and disease severity (Miyazaki et al., 2002). Self et al. (2000) placed a force pad between the brace and the user on the lateral epicondyle, and used a simple 2-dimensional
model to compute the brace moment. This analysis showed significant decreases in the external knee adduction moment at 20% and 25% of stance phase during walking, and an estimated brace moment of 3.0 Nm. Schmalz et al. (2010) measured brace deformation during walking using a motion-capture system. Using these data, and a linear brace model derived previously using a mechanical apparatus; a mean brace moment of 3.3 Nm was estimated. Pollo et al. (2002) instrumented a single unloader brace with strain gauges located near the lateral knee and a buckle transducer on one strap (Figure 1.5). The brace was adjusted to controlled deflection angles, and the brace moment was measured during walking, resulting in mean brace moments across all conditions of 7.1 Nm. Fantini Pagani et al. (2013) performed a similar experiment, instrumenting a single unloader brace with a strain gauge near the lateral hinge, and measured brace moment during walking for several valgus angle conditions. These studies show that bracing can apply a counteracting moment between 10-20% of the total external adduction moment, possibly resulting in significant load reductions. However, each experimental technique adopted to quantify brace moment has limitations that can influence the accuracy of results.
Figure 1.5: Schematic of experimental setup used to measure brace moment using strain gauges. $M_{H}$ is the moment applied at the knee, $F_1$ is the force applied to the lateral knee, $F_2$ is the reaction force applied to the thigh section, and $F_3$ is the reaction force applied to the shank section (Pollo et al., 2002).

Using lateral force measurements to estimate the brace moment has significant drawbacks. In order to compute the brace moment using lateral force, according to the principle of three-point bending, the length of the thigh and shank lever arms are required (Figure 1.2, C)(Hibbeler, 2003). Self et al. (2000) used the distance from the knee joint, where the lateral force measurements were collected, to the end of the thigh and shank brace sections, as the lever arms to estimate the brace moment. However, as unloader braces attach with straps at the brace ends and near the brace knee joint, the braces apply
pressures in several locations. To adopt the three-point bending model, the forces applied to the shank and the thigh must be resolved into single point forces, representing the net force acting on either segment. As unloader braces apply pressure between the knee and the brace ends, it is unlikely that the thigh and shank lever arms are the entire length of brace, but are smaller, depending on the location and magnitudes of the pressures between the brace and the user. The use of the full brace length for the thigh and shank lever arms would only occur if a single point load was applied to each brace section at each end, which does not occur during in vivo brace use. Therefore, without a method to accurately measure the thigh and shank lever arms of the brace, using lateral force alone proves ineffective to estimate the brace moment.

Approximating the brace moment using brace deflection proves limited due to difficulties accurately measuring brace stiffness in vivo. Schmalz et al. (2010) and Kutzer et al. (2011) used mechanical testing apparatuses to estimate brace stiffness. In these tests, the brace was attached to a rigid apparatus, and brace deformation was measured in terms of the force applied (Figure 1.6). However, the attachment of the brace to the testing apparatus can affect stiffness measurements. As the brace is deflected, the straps near the knee contact the apparatus and bind, applying a force to the lateral beam of the brace near the knee (Figure 1.6, Top). If the apparatus were constructed using compressible materials (Figure 1.6, Bottom), such as foam, when the brace is deflected, the apparatus would compress in response to the force applied by the straps (Figure 1.6, Bottom, B), and undergo a larger deflection for a given applied force (Figure 1.6, Bottom, δ2). With a rigid apparatus however, there would be no compression (Figure 1.6, Top, A), and the measured
deflection (Figure 1.6, Top, $\delta_1$) would therefore be smaller for the same force, resulting in a larger stiffness measurement. As the braces are attached to the leg of users, where soft-tissue deformation occurs in response to an applied force, brace stiffness measured using a rigid testing apparatus could therefore be significantly higher than in vivo brace stiffness. Without a method to validate the mechanical stiffness of the brace to in vivo stiffness, it is uncertain whether the computed values of brace moment are accurate, revealing a limitation of this method.

![Figure 1.6: Schematic of stiffness testing apparatus used to examine unloader braces, showing the effect of compliant versus rigid supports. When using rigid supports (Top), the brace straps near the knee (Top, A) bind against the apparatus. However, when using compliant supports such as form (Bottom), the brace straps near the knee compress (Bottom, B). The result is a larger deflection for compliant supports (Bottom, $\delta_2$) versus rigid supports (Top, $\delta_1$) for the same applied load ($\vec{F}_k$), suggesting that the testing apparatus can influence the measured stiffness.](image)
In addition to the limitations previously discussed, all studies have neglected to measure the pressure distributions between the brace and the user (Figure 1.2, B), which are important as they can influence the brace moment. Considering the principle of three-point bending, lateral knee force (Figure 1.2, C), $\bar{F}_K$ and the length of the thigh (Figure 1.2, C), $\bar{d}_T$ and shank (Figure 1.2, C), $\bar{d}_S$ lever arms can affect the brace moment (Hibbeler, 2003). Turning adjustment screws on the lateral side of the brace (Figure 1.4) can control the force on the lateral knee, however the length of the shank and thigh lever arms are dependent on brace fit and design, and governed by the pressure distributions between the user and the brace. Larger pressures on the medial side compared to the lateral side, located at further distances from the knee, result in a larger lever arm, and thus a larger brace moment. By measuring these distributions, and the force applied to the lateral knee, the individual contribution of lateral force and lever arms towards the brace moment can be quantified. This information can be used to explain differences in the brace moment due to change in brace design, which is valuable when improving brace performance.

1.3 Objectives

The purpose of this study was to develop a novel means of analyzing brace mechanics, that uses pressure distribution measurements between the brace and the user and the force applied to the lateral knee. This primary objective was divided into three specific aims: (1) measuring the pressure distributions between the brace and the user, (2) quantifying important aspects of brace mechanics, (3) and comparing two brace designs.
1.3.1 **Aim 1: Pressure distributions**

The first aim was to measure the pressure distributions on the medial and lateral thigh, and to examine how specific design features of the braces can affect these distributions. This was included as the primary objective because the location and magnitudes of these pressures were used to compute the length of the thigh lever arm (discussed in Chapter 2), which directly affects the brace moment. Therefore, linking differences in pressure distributions to design features reveals the impact of specific components on the resulting brace moment. This is useful when evaluating and improving designs, as well as explaining why differences in brace function occur between designs. If successful in isolating the impact of specific design features on brace function, the proposed method would not only quantify the unloading effect of these braces, but also explain how this unloading occurred in terms of brace components, which to our knowledge, has not been performed in previous studies.

1.3.2 **Aim 2: Brace mechanics**

The second aim was to develop a method capable of quantifying different aspects of brace mechanics that are useful to assess brace performance. Five key elements of brace mechanics were identified using our knowledge of brace function as well as results presented in previous studies (Pollo *et al.*, 2002; Self *et al.*, 2000; Schmalz *et al.*, 2010):

1. Thigh lever arm
2. Lateral load
3. Brace deflection
4. Brace moment

5. Brace stiffness

Lateral load and thigh lever arm were included as they are important when computing the brace moment, which relates to the intended function of the braces. Brace deflection (deg) was measured to compute brace stiffness (Nm/deg) using the brace moment (Nm). Brace stiffness was incorporated into the results as one study (Kutzner et al., 2011) showed differences in the brace moment between subjects. We hypothesize that these differences are a result of how the braces were applied to the user in terms of strap tightness and the force on the lateral knee, and not the mechanics of the braces themselves. According to the principle of three-point bending, changes in the force applied to the lateral knee would also cause a change in brace deflection and the brace moment. As brace stiffness normalises the brace moment to the deflection of the brace, it is therefore more independent of brace strap tightness and the force at the lateral knee, and is thus a useful metric when comparing braces.

1.3.3 Aim 3: Two brace comparison

The third and final aim was to determine whether the proposed method is capable of discerning differences in brace mechanics between designs, and linking any observed differences to specific brace components. This is important to enforce the validity of results, as differences in mechanics that cannot be explained using brace design are presumably a result of inaccuracy in the proposed method. Therefore, two braces were selected that employ the same principles of operation, but have significant design differences.
The braces selected were the DonJoy OA assist single hinge (H1) brace, and the DonJoy OA adjuster 3 double-hinge (H2) brace (Figure 1.7)(DJO Global, Vista, California). In terms of geometry, H1 has a single-hinge located on the lateral side of the knee (Figure 1.7, Right), while H2 has a double-hinge, on both the lateral and medial sides of the knee (Figure 1.7, Left). The mechanism used to increase the force on the lateral knee also differs between these braces. For H1, turning two screws on the lateral hinge moves a pad in the medial direction, which increases the force applied to the lateral knee of the user (Figure 1.8, Right). For H2, increasing the force applied to the lateral knee is achieved again by turning two screws, but in this case, they are located on the lateral side, near the thigh and shank sections of the brace (Figure 1.8, Left). These screws turn gears, which alter the angle of the arms attached to the lateral hinge, thus applying pressure to the lateral knee.
Figure 1.7: Front view of DonJoy OA assist single hinge (Right) and DonJoy OA adjuster 3 double-hinge (Left) braces
Figure 1.8: Side view of H2 (Left) and H1 (Right), highlighting the mechanisms used to increase the force applied to the lateral knee (Left, 1) (Right, 2). For H2 the gear (Left, 4) that changes the lateral beam angle is shown. For H1 (Right, 2) the two adjustments screws on the lateral hinge (Right, 3) are highlighted.
Chapter 2

Methods

An essential aspect of this study is the loading case assumed for the analysis of brace mechanics. According to manufacturer specifications (DJO Global, Vista, California) and previous studies that examined similar designs (Schmalz et al., 2010; Self et al., 2000; Kutzner et al., 2011), the braces apply a three-point bending load to the subject. To ensure that the results reported from this study were comparable to previous studies, and to simplify the analysis, a three-point bending model was used to examine the braces. This section provides an overview of three-point bending, and what factors can influence the internal bending moment. From this overview, the individual components used to compute the internal bending moment are discussed, including a description of the apparatuses and computational techniques. The limitations of the assumptions used for this loading case are described, addressing their possible impact on the accuracy of results.

2.1 Three-point bending of a beam

The analysis performed in this study assumed that brace operation was governed by non-
symmetrical three-point bending of a beam (Figure 2.1, 1). In this loading, point loads are applied to a beam, at unequal distances from either end. A roller and a pin joint, neither of which can support a bending moment, are positioned at either ends of the beam (Figure 2.1, 1). Using this loading description, a free body diagram was produced (Figure 2.1, 2), which was used to derive a shear force diagram (Figure 2.1, 3) and the resulting internal bending moment diagram (Figure 2.1, 4).

Shear force in the beam begins at a constant positive value, according to the magnitude of the reaction force at the first beam end (Figure 2.1, point A). This value remains constant as a function of distance along the beam, until it passes the position of the point load applied to the beam (Figure 2.1, point B), where internal shear force immediately decreases to a negative value. This negative shear remains constant as a function of distance along the beam for the remainder of the beam length (Figure 2.1, point C).

The internal bending moment of the beam starts at zero (Figure 2.1, point A) and increases linearly to the maximum value, occurring at the position of the applied point load (Figure 2.1, point B). The bending moment decreases linearly from this maximum, returning to zero at the other end of the beam (Figure 2.1, point C).

The maximum internal bending moment was derived by performing a force and moment balance of the free-body diagram (Figure 2.1, 2), assuming a static loading state.
Figure 2.1: Three-point bending of a beam, showing beam on supports (1), free body diagram of this loading (2), internal shear force diagram (3), and internal bending moment diagram (4).

Summing the forces in the y direction, and isolating for the point force applied to point C of the beam:
\[ \Sigma F_y = 0 = \vec{F}_B - \vec{F}_C - \vec{F}_A \quad (2.1.0) \]

\[ \vec{F}_C = \vec{F}_B - \vec{F}_A \quad (2.1.1) \]

Summing the moments about point B, and isolating for the point force applied to point C:

\[ \Sigma M_B = 0 = \vec{F}_A \cdot \vec{d}_{AB} - \vec{F}_C \cdot \vec{d}_{BC} \quad (2.2.0) \]

\[ \vec{F}_C = \frac{\vec{F}_A \cdot \vec{d}_{AB}}{\vec{d}_{BC}} \quad (2.2.1) \]

Equating 2.1.1 and 2.2.1, and isolating for the point force applied to point A of the beam:

\[ \frac{\vec{F}_A \cdot \vec{d}_{AB}}{\vec{d}_{BC}} = \vec{F}_B - \vec{F}_A \quad (2.3.0) \]

\[ \vec{F}_A = \frac{\vec{F}_B \cdot \vec{d}_{BC}}{(\vec{d}_{AB} + \vec{d}_{BC})} \quad (2.3.1) \]

Using the result shown in Equation 2.3.1, a section of the beam was taken to derive the equation of internal bending moment between point A and point B (point A defined as x = 0):

\[ M(x)_{A\rightarrow B} = \vec{F}_A \cdot x \quad (2.4.0) \]

Substituting the result shown in Equation 2.3.1 into Equation 2.4.0:

\[ M(x)_{A\rightarrow B} = \frac{\vec{F}_B \cdot \vec{d}_{BC}}{(\vec{d}_{AB} + \vec{d}_{BC})} \cdot x \quad (2.4.1) \]

Substituting \( x = \vec{d}_{AB} \) into Equation 2.4.1, the maximum internal bending moment in the beam (Equation 2.4.2) was derived, as a function of the point load applied to point B (\( \vec{F}_B \)), and the distances between point B and the beam ends (\( \vec{d}_{AB} \) and \( \vec{d}_{BC} \)):

\[ M_{MAX} = \frac{\vec{F}_B \cdot \vec{d}_{AB} \cdot \vec{d}_{BC}}{(\vec{d}_{AB} + \vec{d}_{BC})} \quad (2.4.2) \]

where:

\[ M(x)_{A\rightarrow B} \text{ is the internal bending moment as a function of distance along the beam} \]
between points A and B

\[ M_{\text{MAX}} \] — the maximum internal bending moment, occurring at point B

\[ \hat{F}_{Ay} \] — the vertical force applied at point A

\[ \hat{F}_{By} \] — the vertical force applied at point B

\[ \hat{F}_{Cy} \] — the vertical force applied at point C

\[ \tilde{d}_{AB} \] — the horizontal distance between point B and point A

\[ \tilde{d}_{BC} \] — the horizontal distance between point B and point C

According to this derivation (Equation 2.4.2), the maximum internal bending moment is sensitive to three factors, being the magnitude of the applied point load (\( \hat{F}_{By} \)), the position of the applied point load relative to the beam ends (\( \tilde{d}_{AB} \) and \( \tilde{d}_{BC} \)), and the total beam length (\( \tilde{d}_{AB} + \tilde{d}_{BC} \)). Assuming a constant position of the point load, the bending moment is linearly proportional to both beam length and the magnitude of the point load. Bending moment however is non-linearly affected by the position of the point load relative to either end. With a fixed beam length and point load magnitude, maximum internal bending moment occurs when the point load is positioned at the center of the beam. In this situation, the reaction forces at the beam-ends are equal, and the maximum shear force within the beam is minimized.

### 2.2 Three-point bending of a brace

In terms of brace operation *in vivo*, the braces apply five distributed loads to the subject (Figure 1.2, Center) in the frontal plane (ignoring shear forces). Two distributed loads are
applied to the thigh (Figure 1.2, \( \vec{F}_{T1} \) and \( \vec{F}_{T2} \)) and the shank (Figure 1.2, \( \vec{F}_{S1} \) and \( \vec{F}_{S2} \)), resulting in two net forces in the lateral direction acting on either segment (Figure 1.2, \( \vec{F}_{SHANK} \) and \( \vec{F}_{THIGH} \)). The fifth distributed load occurs as a result of contact between the lateral hinge of the brace and the lateral knee of users (Figure 1.2, \( \vec{F}_{K} \)). This contact applies a net load in the medial direction (Figure 1.2, \( \vec{F}_{KNEE} \)), which combined with the laterally directed forces, results in a bending moment applied to the knee. According to this loading description, in vivo brace operation resembles the loading of three-point bending presented in Section 2.1. The force applied to the lateral knee (Figure 1.2, \( \vec{F}_{KNEE} \)) is represented by the point force applied between the beam ends (Figure 2.1, \( \vec{F}_{B_y} \)), and the net forces applied to the thigh (Figure 1.2, \( \vec{F}_{THIGH} \)) and shank (Figure 1.2, \( \vec{F}_{SHANK} \)) are represented by the reaction forces at the beam ends (Figure 2.1, \( \vec{F}_{A_y} \) and \( \vec{F}_{C_y} \)). The similarities between the forces applied during in vivo brace use and a three-point bending model suggests that its use is appropriate to analyze brace function.

Accordingly, a three-point bending model was used to design an experiment to calculate the maximum internal bending moment within the brace. Using Equation 2.4.2, this requires the measurement of three components, being the force applied to the lateral knee of users, and the thigh and shank lever arm distances. The force between the brace and the user on the lateral knee was measured directly using a load cell (Section 2.1), and pressure mats were positioned between the brace and the user to estimate the thigh lever arm (Equation 2.4.2, \( \vec{d}_{AB} \)). However, the pressure mat data was insufficient to measure the magnitude of the thigh reaction force, as the sensing areas of the pressure mats were not
sufficiently large to capture the entire contact of the thigh section of the brace with the user. Furthermore, as the experimental setup was limited to two pressure mats, the magnitude of the shank reaction force and the shank lever arm was not measured. Therefore, the brace moment was estimated based on experimental measurements of lateral load (Section 2.2) and thigh lever arm (Section 2.3), and assumed values of shank lever arm (Section 2.4) based on pilot testing data (Appendix C)(Figure C.1) and brace geometry.

2.3 Lateral load

Lateral load was measured in this study using a load sensor (Tekscan, Model A401), which operates according to the piezoresistive effect. When the sensor is loaded, the resistances of the semiconductors within are altered. With a constant excitation voltage, and a calibration trial where force is related to output voltage, the force applied to the sensor can be computed (Tekscan, Model A401). This sensor was selected primary due its relatively inexpensive cost, and performance deemed adequate for this experiment (Hollinger et al., 2006).

This sensor was placed within an aluminum housing (32 mm diameter x 8 mm thick) to ensure that axial loading was measured, as these sensors are sensitive to shear forces (Hollinger et al., 2006). Attached to this housing was a custom rigid tracking cluster consisting of four motion capture markers (Figure 2.3, 2). These were used to define the position and orientation of the load cell during the experiment. Wooden dowels were attached to both sides of the aluminum housing, to ensure that the sensor measured the
entire load transferred to the lateral hinge of the brace (Figure 2.3, 1).

Prior to experimentation, this setup was conditioned and calibrated according to manufacturer’s specifications (Tekscan, Model A401). This included pre-loading the sensor, and performing a calibration trial, where a force was manually applied to the sensor while the sensor was situation on a force plate, and the output voltage was related to the measured force. After this calibration was complete, the load cell setup (consisting of the load sensor, the aluminum housing, and the rigid tracking cluster) was placed between the user and the brace on the lateral knee, measuring the magnitude and orientation of the force applied to the lateral knee.

2.4 Thigh lever arm

The thigh lever arm (Figure 2.2, $\vec{d}_T$) was computed using data from two Novel Pliance pressure mats (model Elastisens ES-64-54/216-14, Novel, Munchen, Germany), each consisting of 64 pressure cells, in 16X4 formations. These mats measure pressure in each cell using capacitive transducers. Each cell consists of two metal capacitors, one attached to a diaphragm, and one attached to a ceramic medium. In response to changes in pressure, the capacitor attached to the diaphragm deflects, changing the distance between the two capacitors and thus capacitance, which is measured by an integrated circuit. These changes in capacitance are converted to voltage, and pressure using the voltage pressure relationship of the sensor (Novel, Munchen, Germany).

These two pressure mats were placed between the brace and the subject, under the lateral
and medial sides of the thigh section of the brace. These positions were selected as they measure the normal force of the brace in the same direction as the applied force at the knee, in the frontal plane of the thigh. Therefore, they capture the forces that contribute most significantly to the brace moment.

Figure 2.2: Schematic of the magnitudes and positions of the force distributions (Left) applied to the thigh section of the brace on the medial ($\vec{F}_{T1}, \vec{d}_{T1}$) and lateral sides ($\vec{F}_{T2}, \vec{d}_{T2}$), as well as the position ($\vec{d}_{T}$) and magnitude ($\vec{F}_{T}$) of an equivalent point load applied to the thigh section of the brace (Right)

Data from the pressure mats yielded pressure distributions on the medial and lateral sides of the thigh. Using the geometry of the pressure mats, these pressure distributions were converted to force distributions. Furthermore, the location and orientation of the mats
relative to the knee were measured during the experiment using motion capture markers (Figure 2.3, 3). Therefore, the position, orientation and magnitude of the normal forces between the user and the brace on the lateral and medial sides of the thigh were measured (Figure 2.3, Left). These data were converted into the thigh coordinate system using joint angles exported from Visual3D (C-Motion, Germantown, MD, USA), resulting in normal forces resolved in the frontal plane of the thigh. The accuracy of this process was validated using Visual3D, and is described in Appendix D. Using these data, a moment balance about the knee was performed, whose result (along with the magnitude of the force distributions) was used to estimate the position (Figure 2.2, $\vec{d}_r$) of a net reaction force. The position of this point load relative to the knee was used as the thigh lever arm when computing the brace moment.

**Figure 2.3:** Schematic of experimental setup, showing the minimum and maximum thigh ($\vec{d}_{T_{\text{min}}}, \vec{d}_{T_{\text{max}}}$) and shank ($\vec{d}_{S_{\text{min}}}, \vec{d}_{S_{\text{max}}}$) lever arms (Left). The load cell positioned between the brace on the user on the lateral knee is highlighted (1), as well as the tracking cluster used to locate the position of this load cell during the experiment (2). The lateral pressure mat is also highlighted (3), showing the motion capture markers placed on three of the corners to measure the position and orientation of the pressure.
2.5 Shank lever arm

The shank lever arm was estimated considering brace geometry and data collected during pilot testing. A preliminary analysis of brace geometry was performed to determine the minimum and maximum lengths of the thigh and shank lever arms (Figure 2.3). For both braces, the possible shank lever arms were located from the proximal shank strap (Figure 2.3, $d_{smin}$) to the end of the shank section of the brace (Figure 2.3, $d_{smax}$), while the possible thigh lever arms were located from the distal thigh strap (Figure 2.3, $d_{tmin}$) to the end of the thigh section of the brace (Figure 2.3, $d_{tmax}$). Two pilot subjects were tested, with the pressure mats positioned under the thigh section of the brace in the first experiment, and under the shank section of the brace in the second experiment. Using these data, the thigh and shank lever arms were separately computed using the procedure outlined in Section 2.4. Between subjects, the variability in the shank lever arm (+/- 1 cm) was smaller than the variability in the thigh lever arm (+/- 2 cm), therefore the two pressure mats were used to measure the thigh lever arm during the primary data collection, and the shank lever arm was estimated based on the pilot study results. The mean shank lever arm was located near the distal shank strap for both braces ($H2 = 11$ cm, $H1 = 15$ cm), both locations falling within the range of possible shank lever arm distances determined based on brace geometry (Figure 2.3). When computing the brace moment, the shank lever arms were held constant for both braces, using the mean values computed for the two pilot subjects.
2.6 Three-point bending loading limitations

Brace operation in this experiment was studied using a simplified loading case, being non-symmetrical three-point bending. This analysis adopted several simplifications and assumptions, which were examined to estimate their impact on the accuracy of results. This was performed to assess the suitability of the proposed method in analyzing unloader braces. The most significant limitations of this simplified loading analysis were ignoring shear forces between the brace and the user, assuming a static loading state, and the use of point loads as opposed to distributed loads. This section summarizes these limitations, why they were necessary in the analysis, and their possible impact on the accuracy on results.

The first limitation relates to a primary requirement for three-point bending; the beam ends were assumed to be resting on a pin and roller, implying that zero moment and purely vertical reaction forces occurred at either end. This assumption therefore ignores any shear forces between the brace and the user, which would be applied in the horizontal direction. Ignoring shear forces was performed to simplify the analysis, but considered the interaction of the brace with the underlying soft tissue of the user. Literature reports that soft tissue deformation occurs when a small amount of shear force is applied (Andersen et al., 2010; Pierrat et al., 2015). Therefore, substantial brace movement would accompany the presence of significant shear forces. Although brace movement was not quantified, the position of the brace was consistent between trials for all subjects, suggesting that brace movement was not significant. This presumably small movement, as well as the small distance at which the shear forces act with respect to the knee, imply that shear forces did
not have a significant impact on the computed brace moment.

The second assumption was that static loading occurred, indicating that the braces experienced zero acceleration during the experiment. This assumption was made again to simplify analysis, however its impact on results was deemed limited for two reasons. These reasons relate to the procedure used when performing a force summation, whose result is equated to the mass of the object multiplied by the acceleration of the object, which in this analysis, was set to zero. As the braces are relatively light-weight (under 1 kg), and experienced little acceleration during the trials, both terms (mass and acceleration) used in the force balance were presumably small. The combination of these two factors makes the assumption of static loading relatively valid, therefore having a minimal impact on the accuracy of results.

The loads applied to the beam were assumed to be point loads, while the loads applied to the brace are clearly distributed. However, the effect of this assumption is limited based on the method used to calculate the position of the point loads relative to the knee. In this calculation, the moment caused by the distributed loads was used to compute the distance between the knee and the point loads applied to the thigh or shank. Therefore, the resulting brace moment at the knee is equivalent, whether the system is modelled using point loads or using distributed loads, by modifying the position of the point load to achieve a comparable result. Therefore, simplifying the distributed loads to points loads had a small impact on the accuracy of results.
According to this analysis, the limitations caused by the simplified three-point bending loading had a minimal impact on results. Small brace movement suggested small shear forces, which enforced the use of a roller and pin joint to support the beam-ends. Little brace acceleration, as well as the small mass of the braces, indicated that the static loading assumption had a minimal impact on results. Finally, the simplification of the distributed loads to point loads between the brace and the user was accounted for by adjusting the length of the beam, to achieve an equivalent result whether distributed or point loads were used. Therefore, the use of a simplified three-point bending model to analyze brace mechanics was deemed appropriate based on this qualitative assessment. Fully quantifying the effect of these assumptions however requires the use of a gold standard in brace moment measurement.
Chapter 3

A novel method to analyse the mechanics of unloader braces for medial knee osteoarthritis

This chapter has been prepared in the format of a journal article, to be submitted to the Journal of Biomedical Engineering.

3.1 Background

Medial knee osteoarthritis is the degradation of cartilage and the underlying bone in the medial compartment of the knee. Cartilage degradation can occur for a variety of reasons, but is typically associated with excessive forces in the joint (Miyazaki et al., 2002). As direct in vivo measurement of joint forces is invasive, external loads have been used instead. Of particular interest is the external knee adduction moment, as it describes the distribution
of the external loads through the medial and lateral sides of the knee (Kutzner et al., 2011). Higher external adduction moment can indicate that a larger proportion of the external load is being transferred through the medial compartment, possibly resulting in higher forces on the cartilage (Kutzner et al., 2011). Furthermore, cross-sectional studies have found that the magnitude of the external knee adduction moment is an indicator of disease severity (Miyazaki et al., 2002), making external knee adduction moment reduction a focus for several treatment options (Pollo et al., 2002; Street et al., 2013).

Off-the-shelf unloader knee braces are an example of a treatment option designed to reduce the external knee adduction moment, to decrease pain and increase function for prescribed individuals. In theory, these braces reduce external knee adduction moment through the application of an external abduction moment (brace moment) that can be modelled using the principle of three-point bending (Schmalz et al., 2010). One rigid portion of the brace attaches to the shank, while another rigid portion attaches to the thigh. These are connected by a joint, which contacts the lateral knee, and applies a medially-directed force to the lateral epicondyle. This epicondyle force, as well as the laterally-directed forces on the shank and thigh, results in the application of an abduction moment to the knee joint, which in theory reduces compressive loads in the medial compartment of the knee. Users have the ability to adjust the applied moment at the knee, according to their comfort levels, by turning screws on the lateral side of the brace, which increase the force applied to the lateral epicondyle.

In addition to applying an external moment, unloader braces could influence the external
knee adduction moment through two secondary mechanisms, specifically altered muscle activations and changes in gait kinematics (Ramset et al., 2007), both of which may be associated with brace use. Because the contribution of each of these mechanisms towards external knee adduction moment reduction is uncertain, it is difficult to establish which factor is the most influential. This is important as each factor can significantly affect brace design. For instance, if the effects of altered muscle activation dominate, more minimalistic designs could offer the same relief for patients, and increase the likelihood that the braces are worn (Brouwer et al., 2010). Alternatively, if the brace moment is the most influential factor in reducing joint loads, current brace designs are suitable, as the mechanism of force reduction is in accordance with the intended purpose of the brace (Ramsey et al., 2007).

Therefore, it is important to quantify the brace moment to determine its contribution to the unloading effect of knee braces, in order to assess the appropriateness of unloader brace design.

Previous studies have quantified the brace moment through direct measurement (Pollo et al., 2002; Fantini Pagani et al., 2013) using the force applied to the lateral knee (Self et al., 2000) or using brace deflection (Shmalz et al., 2010). Self et al. (2000) inserted a force bladder between the brace and the user, on the lateral epicondyle of the knee, and estimated the brace moment using this force measurement and lever arms assumed using brace geometry. This method is minimally invasive towards the brace and the patient, however it is uncertain whether geometry is sufficient to accurately define brace lever arms, because the braces apply pressure distributions to the user, and not point loads at the brace ends. Schmalz et al. (2010) measured brace deformation using a motion capture
system, and computed the brace moment using brace stiffness calculated using a mechanical test. Although this method is applicable to various brace designs, Schmalz et al. (2010) derived the stiffness model while the brace was in a fully extended position, and measured brace deflection using only three motion capture markers. This technique results in accurate measurements when the brace is fully extended, however error will increase as flexion increases because of difficulties resolving adduction deflection from flexion. Furthermore, brace stiffness measured using a mechanical apparatus could be different to \textit{in vivo} brace stiffness because of the compliance of soft tissue compared to a rigid testing apparatus. Other studies (Pollo \textit{et al.}, 2002; Fantini Pagani \textit{et al.}, 2013) directly measured the brace moment by instrumenting an unloader brace. Pollo \textit{et al.} (2002) and Fantini Pagani \textit{et al.} (2013) fitted a single brace with strain gauges near the lateral hinge, and measured brace moment during walking for 4 valgus angle conditions. Instrumenting braces provides an accurate means of measuring brace moment, however the mechanical integrity of the brace is altered during the experimental setup. Despite the limitations of previous studies, similar brace moment magnitudes were calculated, being roughly 10-20\% of the total external knee adduction moment.

All studies, however, have neglected the brace pressure distributions on the thigh and shank of users. These are important to consider, as their magnitudes and positions influence the brace moment. Considering the principle of three-point bending, the brace moment is affected by two factors, namely the lateral force at the knee, and the length of the lever arms of the shank and thigh sections of the brace (Figure 3.4). Lateral force can be directly controlled by the user using adjustment screws, however, the length of the lever
arms for the shank and thigh are defined by the pressure distributions on the medial and lateral sides, which are affected by brace fit and design. Larger pressures, located at greater distances from the knee, on the medial side compared to the lateral side, result in a larger lever arm, and thus a larger brace moment. By measuring these distributions, and lateral force, the individual contributions towards the brace moment of brace lever arms and the force applied to the lateral knee could be more clearly characterized. This information is valuable as it can help explain differences in the brace moment as a result of changes in design, which is important to improve brace effectiveness.

Therefore, the purpose of this study is to provide a novel means of analyzing brace mechanics, specifically by measuring the pressure distributions and lateral force applied at the knee between the brace and the user. Our secondary objective was to compare two braces, to establish whether the proposed method is suitable to identify differences in the functionality of different brace designs.

3.2 Methods

The experimental procedure consisted of a series of static calibration and treadmill walking trials for two different brace designs. Data from these measurements were used to quantify the applied brace moment and brace stiffness for both braces, in terms of the force applied to the lateral knee, the length of the thigh lever arm, and the adduction deflection of the brace.

3.2.1 Braces
Two unloader knee braces were analysed in this study: the DonJoy OA assist single hinge (H1) brace, and the DonJoy OA adjuster 3 double-hinge (H2) brace (Figure 3.1)(DJO Global, Vista, California). These braces employ the same three-point-bending mechanism of operation, but have significant design differences (DJO Global, Vista, California). Namely, the OA assist has a single lateral beam (Figure 3.1, Right), while the OA adjuster 3 has a lateral beam as well as a medial beam (Figure 3.1, Left). All subjects were fitted with the extra large brace, to avoid potential differences in brace function as a result of brace size

Figure 3.1: DonJoy OA assist single hinge (Right) and DonJoy OA adjuster 3 double-hinge (Left) braces

3.2.2 Experimental setup
This study consisted of a convenience sample (laboratory members) of five healthy participants, one female and four males, with no known lower limb abnormalities, and ages ranging from 19 to 32. Manufacturer’s specifications indicate that sleeves can be worn under braces, to reduce movement of the brace and increase comfort (DJO Global, Vista, California). Accordingly, athletic wraps were placed around the thigh and shank of each participant. This resulted in a consistent interface between the braces and the subjects.

Thirteen passive reflective motion capture markers were attached to each brace. Four 9.25 mm markers were placed on both the lateral shank and lateral thigh sections, proximal and distal to the straps closest to the knee joint. Four additional 12.7 mm markers were placed on the proximal anterior portion of the thigh section of the brace. A final 9.25 mm marker was placed on the lateral side of the brace that contacts the lateral epicondyle of the knee (Figure 3.2). Marker positions were recorded at 200 Hz using a passive 12-camera motion capture system (Qualisys, Gothenburg, Sweden). Ground reaction force data were recorded synchronously at 1000 Hz using a tandem instrumented AMTI treadmill (AMTI, Massachusetts).
Figure 3.2: Sketch of full experimental setup for H2, showing frontal (Left) and sagittal (Right) views. This schematic includes the lateral and medial pressure mats (1), motion capture marker (2), the brace (3), the load sensor and rigid tracking cluster between the user and the brace on the lateral knee (4), the minimum ($d_{\text{SMIN}}$) and maximum ($d_{\text{SMAX}}$) distances for the shank reaction, and the inferior super directions used to define the brace coordinate systems ($V_2, V_1$).

The first brace, selected at random, was attached to the subject according to manufacturer’s specifications (DJO Global, Vista, California). Two Novel Pliance pressure mats (model Elastisens ES-64-54/216-14, Novel, Munchen, Germany), 54 mm wide and 216 mm long and consisting of 64 (16x4) 13.5 x 13.5 mm pressure cells, were placed between the subject’s leg and the brace. The pressure mats were positioned under the thigh section of the brace, one on the medial side and one on the lateral side (Figure 3.2). Three motion capture markers were placed on each of the two pressure mats, at the origin
and two corners. These markers were used to define the location and orientation of the pressure mats relative to the four markers placed on the rigid thigh section of the brace during an initial static trial. With these locations and orientations, the positions of the pressure mats, relative to the brace, were reconstructed during the walking trials. Data from the pressure mats, whose performance is described by Giacomozzi (2010), were recorded at 50 Hz using the Novel Pliance X/B software.

Two piezoresistive load sensors (Tekscan, Model A401), with performance described by Hollinder (2006), were conditioned and calibrated according to manufacturer specifications (Tekscan, Model A401). The first sensor was positioned under the lateral force mat, proximal to the thigh section of the brace. This was included in the experimental setup solely to provide a means of synchronising the data collected from the Novel pressure mats with the load sensor data and motion capture data. As these piezoresistive load sensors are sensitive to shear forces (Hollinger et al., 2006), the second load sensor was placed in a custom cylindrical aluminum housing (32 mm diameter x 8 mm thick), to isolate lateral epicondyle loading between the brace and the subject. A rigid tracking cluster was attached to this aluminum housing, to record the location and orientation of this force (Figure 3.2). Analog data from the sensors were amplified using a Quickstart circuit board (Tekscan, FlexiForce Quickstart Board) and sampled synchronously with motion capture data at 1000 Hz using a Qualisys DAQ (Qualisys, Gotenburg, Sweden).
3.2.3 Protocol

After the experimental setup was complete, the first brace was tightened to the maximum tolerable load for each subject. This was achieved by turning two screws on the lateral side of the brace, which increased the pressure that the brace applied to the subject’s lateral epicondyle. A static calibration trial was recorded to register the position of the pressure mats relative to the brace. After the calibration trial was collected, the markers on the pressure mats were removed.

Following calibration, two walking trials of thirty-second duration were collected. At the beginning of each trial, the subject was instructed to press on the lateral pressure pad, under which the force transducer was placed. This resulted in synchronization peaks measured by both the lateral pressure mat and the lateral load sensor (discussed in Section 3.2.4). The treadmill belt speed was increased to 1.3 m/s, which is in the range of comfortable walking speeds for healthy adults (Bohannon et al. 2010). This treadmill speed was constant for all subjects.

After the two walking trials, the brace was removed without altering the tightening screws. A static trial was collected of the brace in a fully extended position and not attached to the subject, to measure the un-deflected posture. This trial was recorded to normalise the brace angles computed in the subsequent experimental analysis to the un-deflected state of the brace. The subject was fitted with the second brace, and the procedure described above was repeated.
3.2.4 Data processing

All data were filtered using a 2nd-order dual-pass Butterworth low pass filter with a cutoff frequency of 6 Hz. As described in Section 3.2.3, pressure mat data were synchronized with the analog and motion capture data using measurements from the lateral force mat and the proximal lateral load cell. Simultaneous peaks in both signals were isolated, and cross-correlation was performed to determine the lag between signals.

Using force data from the instrumented treadmill, three complete gait cycles were isolated for the portion of each walking trial when the subject was at the target walking speed. Stance phase for each gait cycle was defined from heel strike to toe off.

3.2.5 Coordinate systems

Coordinate systems of the brace thigh and shank were defined using the makers placed on the lateral hinge on the brace. A functional flexion axis was first computed in Visual3D (C-Motion, Germantown, MD, USA) using the finite helical axis method (Marin et al., 2003; Schwartz et al., 2005) for the last three strides of the normal walking trials. This axis was defined locally in both the thigh and shank sections of the brace. The inferior-superior direction of the brace was defined using marker positions from calibration trial. This direction was the average of two vectors (Figure 3.2, Right):

1) Inferior anterior marker on the thigh to the superior anterior marker on the shank ($V_1$)
2) Inferior posterior marker on the thigh to the superior posterior marker on the shank ($V_2$)

This inferior-superior vector (average direction of $V_1$ and $V_2$) was defined locally in the thigh and shank sections of the brace, and the adduction axis was defined as the cross product between the inferior-superior direction and the functional flexion axis. Finally, the internal rotation axis was defined as the cross product between the functional flexion axis and the adduction axis.

Euler angles were computed between the brace thigh and brace shank coordinate systems using flexion-adduction-internal rotation as the rotation sequence (Grood et al., 1983).

Two local coordinate systems of the pressure mats were created using the markers placed on the three corners. These coordinate systems were used to transform pressure distributions into the thigh brace frame.

### 3.2.6 Brace moment

Although manufacturers indicate that the braces operate according to the principle of three-point bending (DJO Global, Vista, California), our analysis of *in vivo* brace use revealed that five loads were applied in the frontal plane to the brace. Two distributed loads were applied to both the shank and the thigh sections on the medial and lateral sides, while one distributed load was applied to the lateral knee (Figure 3.3). To simplify the analysis, and to ensure our results were comparable with previous studies (Schmalz et al.,
2010; Self et al., 2000; Kutzner et al., 2011), we converted this measured system of five distributed loads to an equivalent system of three point loads which would generate the same brace moment at the knee.

**Figure 3.3:** Schematic of pressure distributions on lateral knee ($\vec{F}_{LAT}$), medial and lateral thigh ($\vec{F}_{T1}$ and $\vec{F}_{T2}$), and medial and lateral shank ($\vec{F}_{S1}$ and $\vec{F}_{S2}$)
A free body diagram of this simplified loading was produced (Figure 3.4), with three point loads acting on the brace: one at the lateral knee ($\hat{F}_K$), one on the shank section of the brace ($\hat{F}_S$, at a distance $d_S$ from the knee), and one on the thigh section of the brace ($\hat{F}_T$, at a distance $d_T$ from the knee). Lateral knee force ($\hat{F}_K$) was measured directly using the piezoresistive sensor placed between the brace and the user on the lateral epicondyle. Medial and lateral pressure mat data were used to compute the distance from the thigh reaction force to the knee ($d_T$). However, the magnitude of the thigh reaction force ($\hat{F}_T$) could not be determined using the pressure mat data, as the pressure mats did not cover the entire contact of the brace with the thigh of the user. Furthermore, because the shank section of the brace was not fitted with pressure mats, the location ($d_S$) and magnitude ($\hat{F}_S$) of the shank reaction force was not measured. Therefore, we derived an analytical model to solve for the brace moment ($M_{KNEE}$) as a function of experimentally available parameters ($\hat{F}_K$, $d_T$).
Using this free body diagram (Figure 3.4), a force (Equation 3.1.0) and moment (Equation 3.2.0) balance was performed assuming a quasi-static loading state (Anderson et al., 2001) as the braces experienced little acceleration during stance, and are relatively lightweight.

Summing the forces in the x (medial-lateral) direction, and isolating for the point force applied to the shank:

\[
\sum F_x = 0 = \vec{F}_K - \vec{F}_S - \vec{F}_T \tag{3.1.0}
\]

\[
\vec{F}_S = \vec{F}_K - \vec{F}_T \tag{3.1.1}
\]

Summing the moments about point K, and isolating for the point force applied to the shank:
\[
\sum M_x = 0 = -\hat{F}_T \cdot d_T + \hat{F}_S \cdot d_S \tag{3.2.0}
\]
\[
\hat{F}_S = \frac{\hat{F}_T \cdot d_T}{d_S} \tag{3.2.1}
\]

Equating 3.1.1 and 3.2.1, and isolating for the point force applied to the thigh:
\[
\frac{\hat{F}_T \cdot d_T}{d_S} = \hat{F}_K - \hat{F}_T \tag{3.3.0}
\]
\[
\hat{F}_T = \frac{\hat{F}_K \cdot d_s}{(d_T + d_S)} \tag{3.3.1}
\]

The bending moment at the knee (Equation 3.4.1) was derived as a function of the load applied to point \(K\) (\(\hat{F}_K\)), and the positions of the loads applied to \(S\) and \(T\), relative to \(K\) (\(d_S\) and \(d_T\)), by substituting Equation 3.3.1 into Equation 3.4.0.
\[
M_{KNEE} = \hat{F}_T \cdot d_T \tag{3.4.0}
\]
\[
M_{KNEE} = \frac{\hat{F}_K \cdot d_T \cdot d_S}{(d_T + d_S)} \tag{3.4.1}
\]

where:

- \(M_{KNEE}\) – the internal bending moment applied at the knee (point \(K\))
- \(\hat{F}_S\) – the force applied at point \(S\)
- \(\hat{F}_K\) – the force applied at point \(K\) (measured using the lateral load cell)
- \(\hat{F}_T\) – the force applied at point \(T\)
- \(d_S\) – the distance between point \(K\) and point \(S\)
- \(d_T\) – the distance between point \(K\) and point \(T\)

The distance between the lateral knee and the point load applied to the thigh of the brace \((d_T\) in Equation 3.4.1) was computed using data from the pressure mats placed between the user and the brace on the medial and lateral thigh. Measured pressure distributions
were integrated over the sensing area using the sensor geometry to generate force
distributions, which were used to perform a moment balance about the knee. Using the
result from this moment balance, and the force distributions, a single point load was
calculated, positioned at a distance resulting in the same moment. This ensures that the
moment at the knee is equivalent, whether the system is modelled using a point load or
distributed loads.

Pilot testing was performed on two subjects, measuring both shank and thigh reaction
distances for both braces. The shank reaction distances \(d_s\) in Equation 3.4.1 was shown to
have a smaller variability between subjects (+/- 1 cm); therefore it was selected to be
estimated instead of measured during the experiment. The mean shank distance was found
to be located at the top portion of the distal shank strap for both braces \(H2 = 11\) cm, \(H1 =
15\) cm), which fell within the range of possible shank reaction distances determined from
geometric inspection of the braces (Figure 3.2). The shank reaction distance \(d_s\) in
Equation 3.4.1) was held constant for all subjects as the mean value measured in the two
pilot subjects.

### 3.2.7 Brace stiffness

In addition to calculating the brace moment (Nm) using the procedure outlined in Section
3.2.6, brace adduction deflection (deg) was also measured and used to compute brace
stiffness (Nm/deg). Differences in lateral load resulted in changes in brace adduction
deflection as well as the brace moment, therefore inter-subject differences were expected.
However, brace stiffness normalizes the brace moment to the amount of measured
deflection, making it more independent of differences in lateral load, and thus a valuable metric to quantify brace mechanics.

### 3.2.8 Presentation of results

Thigh reaction distance, lateral knee load, brace deflection, brace moment and brace stiffness results were displayed for one representative subject as a percentage of stance phase. Inter-subject comparisons were performed using a paired t-test, using mean values of thigh reaction distance, lateral load, adduction deflection, brace moment, and brace stiffness for each subject at mid-stance (50%). This portion of the stance phase was selected as results are less affected by coordinate system definitions and cross-talk (Brandon et al., 2011). Furthermore, braces are intended to reduce adduction moment in osteoarthritic subjects, which have significantly larger loads at mid-stance (Astephen et al., 2008; Brandon et al., 2011).

### 3.3 Results

For both braces, a lateral pressure peak located under the proximal lateral thigh was observed, which was larger for H2 compared to H1 (Figure 3.5, Top). On the medial side, H1 showed higher pressures under the distal strap, while H2 showed a relatively uniform distribution (Figure 3.5). Between subjects, the magnitude and shape of these pressure distributions varied substantially for both H1 and H2. The pressure distributions also changed throughout the stance phase, for both braces. From early-stance to mid-stance, both braces showed increases in the lateral and the medial pressures (Figure 3.5).
Thigh reaction distance, lateral load, brace moment, and brace stiffness were consistent during stance phase (Figure 3.6). An increase in adduction deflection was observed during early stance for H2 (Figure 3.6, C). Individual subjects, for both braces, exhibited small variability between trials, yielding consistent results and small standard deviations about the mean for all results (Figure 3.6).

Figure 3.5: Frontal plane pressure distributions, for H1 (right) and H2 (left), shown for a single subject at early stance (5%) and mid stance (50% stance) on the lateral (L) and medial (M) sides, with scale (top right) in kPa. The rigid medial section of the H2 brace increases the length of the pressure distribution on the medial side, compared to the H1 brace.
Figure 3.6: Mean and standard deviations for 1 subject as a percentage of stance for H1 (blue) and H2 (green), for thigh reaction distance (A), lateral force (B), adduction deflection (C), brace moment (D) and brace stiffness (E)
Differences in brace mechanics were found between the braces using a paired t-test (Table 3.1). Thigh reaction distance between the two braces was similar, with no statistical difference, and a mean value of 13 cm for H1 and H2. In terms of brace geometry, 13 cm from the knee joint represents a position just distal to the proximal thigh strap for both braces. Lateral force, adduction deflection, and the brace moment were significantly larger for H2 compared to H1. Brace stiffness however was significantly larger for H1 compared to H2. The effect sizes for the comparisons resulting in statistical differences were deemed large, all with values greater than 0.8 (Table 3.1).

An additional brace moment was computed (Equation 3.1) to serve as a comparison to the values calculated using the method outlined in Section 3.2.6 (Table 3.1, Brace Moment*). This calculation utilised the lateral force measurements (Table 3.1) for each subject, and thigh and shank lever arms defined using the full length of the thigh and shank brace sections (H2: \(d_{\text{thigh}} = 20\ \text{cm},\ d_{\text{shank}} = 17.5\ \text{cm}\) (H1: \(d_{\text{thigh}} = 18\ \text{cm},\ d_{\text{shank}} = 18\ \text{cm}\)). These results show an increase in brace moment compared to the values calculated using thigh and shank lever arms measured using pressure distributions.
Table 3.1: Thigh reaction distance, lateral load, adduction deflection, brace moment, and brace stiffness for all
subjects at mid stance, showing mean values, P-values for a paired t-test, and the effect size for each comparison.

An additional column, Brace Moment*, is included, which was calculated using lateral force measurements and
full brace lengths.

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<th>Subject</th>
<th>Thigh Reaction Distance (cm)</th>
<th>Lateral Load (N)</th>
<th>Adduction Deflection (deg)</th>
<th>Brace Moment (Nm)</th>
<th>Brace Stiffness (Nm/deg)</th>
<th>Brace Moment* (Nm)</th>
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<tr>
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3.4 Discussion

The objective of this was study was to provide a novel means of analyzing brace mechanics
by measuring the pressure distributions and lateral force at the knee between the brace
and the user. Inter-brace comparisons resulted in no statistical differences in thigh reaction
distance (p > 0.05), while lateral force (p < 0.01), brace adduction deflection (p = 0.02), and
brace moment (p < 0.01) were larger for H2 than H1, and brace stiffness was greater (p = 0.03) for H1 compared to H2. These results indicate that differences in brace mechanics
between designs can be isolated using this method, which, when combined with pressure
distribution data, can be used to isolate the impact of individual design components on
brace function. Furthermore, the differences observed in thigh reaction distances between
subjects suggest that the use of lateral load alone is insufficient to estimate the brace
moment, and that other measurement techniques are required. These results and
observations provide insight regarding brace function, making this method a reasonable non-invasive means of analyzing unloader braces.

As there is no gold standard in brace moment measurement, it is difficult to assess the accuracy of the proposed method. However the results are comparable to values in literature. Self et al. (2000) reported a brace moment of 3 Nm assuming a lateral load of 40 N, which is consistent with the results shown for H1 (Table 3.1). Pollo et al. (2002) reported a mean brace moment between 5.9 Nm and 11.0 Nm, and Fantini Pagani et al. (2013) reported a mean brace moment of 7.4 Nm, which are higher than those calculated in this study, being 4.6 Nm and 3.4 Nm for H2 and H1 respectively (Table 3.1). Some differences between the values computed here and literature are expected, considering the use of different braces between each study, which, based on the values calculated (Table 3.1) can vary significantly between designs. The brace moments computed in this study are realistic and are comparable to values reported in literature, despite significant procedural and brace differences that can influence results.

The force applied to the lateral knee was statistically different between the brace designs (Table 3.1, p < 0.01). This result is unexpected, as the lateral load was increased to a maximum tolerable level for both braces. Therefore, for individual subjects, this load should be constant, as it reflects subject tolerance and not brace design. However, one difference between the braces that could have influenced this result is the mechanism used to increase the force on the lateral knee. For H2, screws are turned on the proximal thigh and distal shank sections of the brace. These screws turn gears, which increase the angle of
the beams attached to the lateral hinge, thus increasing the applied load to the lateral knee. The mechanism used to increase the lateral knee force for H1 however uses two screws on the lateral hinge, which move a pad contacting the lateral knee in the medial direction. As two screws are used to move this lateral pad, on the anterior and posterior sides of the lateral hinge, turning one screw more than the other would result in uneven forces applied to either the posterior or anterior sides of the lateral knee. Therefore, subjects may have indicated a maximum tolerable load had been achieved when a pressure point was occurring, providing a possible explanation for the lateral load differences between braces. Accordingly, comparing brace stiffness rather than lateral force is a more suitable metric to assess this method.

Brace stiffness and adduction deflection between and H1 and H2 were also significantly different (Table 3.1), which was attributed to differences in design. For H2, when a force is applied to the lateral hinge of the brace, the gears on the proximal thigh and distal shank sections, used to increase the lateral force on the knee, behave like springs. During early loading of the brace, it is possible that the adduction deflection is governed by the stiffness of these gears, and not the stiffness of the material used to construct the lateral beams of the brace. Therefore, the total stiffness for H2 is perhaps a combination of gear stiffness as well as the stiffness of the lateral beams. For H1 however, the thigh and shank sections of the brace are solid, making the achieved adduction deflection a result of lateral beam deformation alone. Assuming the gears have a smaller stiffness than the lateral beams, this design difference could explain the smaller stiffness found H2 compared to H1, which, assuming a constant lateral force, would also explain the smaller adduction deflection for
H1 compared to H2. Therefore, the statistical differences between H1 and H2 in adduction deflection and brace stiffness could be a result of differences in brace design and not the accuracy of the described method.

The thigh reaction distances calculated for H1 and H2 were similar, with a mean value of 13 cm for H1 and 14 cm for H2. To our knowledge, all previous studies have assumed reaction distances for the thigh and shank equal to the full length of the brace to estimate the brace moment (Schmalz et al., 2010; Self et al., 2000). Although there was variability in this result between subjects (Table 3.1), no subject had a thigh reaction distance that was equal to the length of the thigh section of the brace (H1 = 18 cm, H2 = 20 cm). The pressures from this experiment (Figure 3.5) showed medial pressures distributed between the distal thigh strap and the proximal thigh strap, and lateral pressures located near the proximal thigh strap. The resulting thigh reaction distance computed using these distributions, as well as the distributions themselves, suggests that the thigh lever arm is not the entire length of the brace, and can be substantially shorter depending on the subject (Table 3.1). When the brace moment was computed using lateral force measurements and lever arms defined using the full length of the thigh and shank brace sections, substantially larger values were calculated (Table 3.1), being 21-45% (0.6-1.2 Nm) larger for H1, and 45-67% (1.7-3.2 Nm) larger for H2 depending on the subject. Therefore, estimating the brace moment using lateral force and the full brace length may result in computed values that are larger than the actual moment.
There were several limitations in this study that could have influenced the accuracy and consistency of results, most of which relate to the assumptions used to calculate the brace moment according to the principle of three-point bending. The first limitation relates to the assumption that the brace applies three point loads. As distributed loads are clearly applied to the shank and thigh of users, this questions the assumption of three-point bending altogether. However, when calculating the brace moment, the distributed loads were incorporated into the analysis, as they were used to define the position of the reaction force on the thigh. This results in equivalent bending moment at the knee, whether the reaction forces are modeled as point loads or as distributed loads, making the impact of this simplification minimal. Ignoring shear forces is another assumption that could influence the calculated brace moment, which were disregarded to simplify analysis. As soft tissue has very low shear stiffness (Andersen et al., 2010), if significant shear forces were present we would expect to see large motion of the brace with respect to the user’s leg. Although this movement was not quantified, consistent position of the brace was qualitatively observed during and between the walking trials. This suggests insignificant movement of the brace with respect to the user, which combined with the small distance at which the shear forces act, make the influence of shear forces on the brace moment likely minimal. The third limitation relates to the shank reaction distances, which were assumed according to brace geometry. This assumption occurred to simplify the experimental setup, and pilot studies showed an increased variability in thigh reaction distance compared to shank reaction distance. Error due to this approximation was analyzed by examining the sensitivity of brace stiffness to changes in shank reaction distance. This analysis showed a 0.02 Nm/deg change in brace stiffness per 1 cm change in shank reaction distance for both
braces, making its effect on results limited compared to other sources of experimental error. However, in order to validate the moments calculated using this method, and quantify the impact of these assumptions, a gold standard is required for comparison.

Another limitation is that control subjects were examined, and not subjects with osteoarthritis. Between an asymptomatic and an osteoarthritic population, there exist significant differences, such as a higher body mass index (Hochberg et al., 1995) for the osteoarthritic population, and therefore an increase in soft tissue. Soft tissue could affect the measured pressure distributions, and change the calculated thigh reaction distance, which alters the brace moment and brace stiffness. It is difficult to estimate the effect of soft tissue on brace mechanics, however if changes in soft tissue only alter reaction distances, their effect may be limited, as brace stiffness was not very sensitive to this measurement (0.02 Nm/deg per cm). Furthermore, the method developed in this study could easily be used to examine in vivo brace mechanics in an osteoarthritic population.

The method described in this study has significant advantages, and some disadvantages, compared to other procedures used to understand brace mechanics. The primary advantage is that pressure distributions can be used to better estimate the position of the thigh lever arm, which based on these results, is not equal to the length of the brace. Furthermore, these pressure distributions can be used to identify the impact of brace components on the brace moment. We have shown that the distal thigh strap increases medial pressures near the knee (Figure 3.5), resulting in a reduction of thigh reaction distance, and therefore a reduction in the brace moment. Without pressure distributions,
the cause of brace moment reduction is not evident, making their use valuable when explaining differences in the brace moment between designs. One disadvantage of this method is that the load cell between the brace and the lateral knee could affect brace function. It is therefore important to ensure that the size and discomfort caused by this load cell is minimized in future experimentation.

In conclusion, the results from this study indicate that this method is a reasonable means of analyzing brace mechanics, showing differences in brace function between designs. It allows the unloading effect of braces to be quantified without brace modification, while providing pressure mat information that is valuable to analyze brace function. Overall, these quantifications provide a means to improve brace design, and thus patient care. Future studies include the validation of the brace moments with a gold standard, to assess the accuracy of results.
Chapter 4

*Unloader brace assessment*

Using some key results presented in Chapter 3, the unloader braces examined in this study were assessed. This included a functional assessment, comparing the calculated brace moments to typical external knee adduction moments, to determine if bracing could significantly impact external forces. Following this comparison, trends in pressure distributions were used to identify individual brace components that could have reduced the thigh lever arm distances for both braces. Using this information, a new brace design was proposed that addresses the drawbacks of these individual components, with the overall objective of increasing the brace moment.

4.1 Clinical significance of the brace moment

The magnitudes of the brace moments were compared to external knee adduction moments calculated for different severities of osteoarthritis, to assess whether clinically significant unloading could be achieved through bracing. Clinical significance was established by quantifying the differences in external knee adduction moment at midstance between moderate and severe groups of osteoarthritis. This difference was used to define clinical significance, as one purpose of these braces is to slow the progression of
moderate and severe osteoarthritis to delay or avoid a total knee replacement (Ramsey et al., 2007). Therefore, load reductions large enough to change the classification of external knee adduction moment at mid-stance from severe, to moderate, were deemed clinically significant.

At mid stance, Astaphen et al. (2008) reported a mean external knee adduction moment of 0.35 Nm/kg for moderate osteoarthritis and 0.40 Nm/kg for severe osteoarthritis. Using a mass of 90 kg, which is the approximate value of the mean mass for the moderate and severe groups (Astaphen et al., 2008), a difference in external knee adduction moment of 4.5 Nm was computed between the these groups at mid-stance. Therefore, brace moments greater than 4.5 Nm were deemed clinically significant.

The mean brace moment values calculated in this study are comparable to this clinically significant difference, with mean values of 3.4 Nm for H1 and 4.6 Nm for H2. However, it is reasonable to assume that the brace moments are larger during real brace use, when the subject is not fitted with the experiment setup that caused discomfort. The most significant difference between the setup and real brace use is the load cell situated between the user and the brace on the lateral epicondyle. The casing in which this load cell was placed is rigid, and subjects indicated there was some discomfort during walking. However during real brace use, the portion of the brace contacting the lateral epicondyle is padded, which could increase comfort, and possibly result in larger lateral force loads. According to the principle of three-point bending, an increase in lateral load would consequently increase the brace moment, suggesting that the calculated brace moments in this study are smaller than the values applied in real brace use, as a result of discomfort in the experimental
setup.

The validity of this hypothesis was examined using data from a different study, which calculated brace adduction deflection for 19 subjects. The aforementioned study used similar coordinate system definitions and analytical procedures as this experiment, for the same two braces. The results showed a mean adduction deflection at mid-stance of 8.0 deg for H1 and 11.0 deg for H2, which are larger than the values calculated in this study, being 5.0 deg for H1 and 10.9 deg for H2. These differences suggest that without the rigid lateral load cell between the user and the brace, it is possible that larger adduction deflections are achieved, possibly caused by larger forces applied to the lateral knee. Therefore, although the brace moments calculated in the current study were slightly more (H2) and slightly less (H1) than the value deemed to provide clinically significant unloading, it is possible that during real brace use the brace moments are larger, indicating that these braces could provide significant unloading and relief for patients with osteoarthritis.

4.2 Effective brace length

Consistent trends in pressure distributions were observed for both braces, which were attributed to specific design features. Identifying components responsible for the observed brace mechanics are important to understand brace function and improve brace effectiveness. This section provides an overview of these pressure distribution trends, the components responsible, as well as their influence on the length of the thigh lever arm. From this overview, an important concept for unloader braces is introduced, called the
effective brace length, which is contrasted with the geometric brace length for several designs.

The first trend observed for both braces was the presence of a pressure peak on the lateral proximal section of the thigh. This pressure peak was predominantly situated under the lateral side of the rigid portion of the brace that wraps from the lateral to the medial side (Figure 3.5). As the forces applied to the lateral thigh section of the brace are in the lateral direction, they effectively reduce the applied moment at the knee, by reducing the length of the thigh lever arm. The significance of this reduction is related to their magnitude as well as their distance from the knee joint. Therefore, limiting the impact of the lateral forces on the brace moment can be achieved by reducing the magnitude of the lateral forces, or reducing the distance between these forces and the knee. As the forces on the lateral side were situated near the proximal end of the braces, their impact was considered substantial for the braces studied.

The second trend observed, which was more evident for H2 compared to H1, was the pressure distribution between the proximal and distal thigh section of the braces on the medial side (Figure 3.5). For both braces, this trend was associated with the rigid medial portion of the brace that applied pressure to the user as a result of the distal thigh strap. In order to increase the thigh lever arm and the brace moment, the medial forces must be as significant as possible, and their distances from the knee joint must be maximized. In this experiment, the distribution of the medial forces between the proximal and distal thigh section effectively reduced the thigh lever arm distance, which negatively impacted the brace moment.
This pressure distribution information reveals an important concept applicable to all unloader braces, called the effective brace length. As opposed to the geometric brace length, which is defined based on brace geometry, the effective brace length is the distance of the thigh and shank lever arms, which is governed by pressure distributions between the brace and the user. The geometric brace length can vary significantly between designs, with some braces attaching at the ankle and hip (MOS Genu, long version, Bauerfiend AG, Germany) while other braces attach more compactly near the knee (DJO Global, Vista, California). To our knowledge however, regardless of geometric brace length, all unloader braces consist of straps near the knee, which attach the brace to the user on the thigh and shank sections. We have shown that these straps, or any other contact between the brace and the user near the knee, can reduce the length of the thigh lever arm, and thus the effective brace length. For example, considering a brace that attaches near the hip and the ankle, as well as near the knee of users, if the hip and ankle straps are loose, and the straps near the knee are tighter, the result would be greater pressures near the knee compared to the hip and ankle. These pressures would ultimately decrease the thigh and shank lever arm distances, resulting in significant differences between the geometric brace length and the effective brace length (Figure 4.1). Therefore it is important to consider the entire contact of the brace with the user when computing the brace moment, as the geometric brace length may be an inaccurate representation of the effective brace length.
Figure 4.1: Schematic of MOS Genu brace with force distributions, showing the possibility of larger forces near the knee joint as a result of the straps near the knee ($\vec{F}_{T1}, \vec{F}_{S1}, Left$), with smaller forces applied to the ankle ($\vec{F}_{S2}, Left$) and near the hip ($\vec{F}_{T2}, Left$). The result of these larger forces near the knee is highlighted on the right, with equivalent net forces applied to the thigh ($\vec{F}_T, Right$) and shank ($\vec{F}_S, Right$) brace sections, contrasting the differences between the thigh lever arm ($d_T, Right$) and the geometric length of the thigh section of the brace ($g_T, Right$), as well as the shank lever arm ($d_S, Right$) and the geometric length of the shank section of the brace ($g_S, Right$). This loading could result in an effective brace length ($\tilde{d}_T + \tilde{d}_S$) much smaller than the geometric brace length ($\tilde{g}_T + \tilde{g}_S$) (MOS Genu, long version, Bauerfiend AG, Germany).
4.3 Brace design

The analysis of the pressure distribution data provided valuable information regarding the impact of specific components on the effective brace length. Two components for each brace were identified that reduced the effective length, being the rigid portion of the brace located on the distal lateral side, and the rigid portion on the medial side of the thigh, which contacted to user near the knee as a result of the distal thigh strap. A modified brace design is proposed (Figure 4.2) with these features altered, in an attempt to improve brace function by increasing the effective brace length.

![Diagram of the proposed brace design](image)

**Figure 4.2:** Schematic of the proposed design, showing frontal (Left) and side (Right) views of the brace. The rigid thigh (1) and shank (4) section are highlighted, as well as the lateral hinge (3), the compressive padding contacting the user on the lateral knee (2), the compressive padding between the rigid thigh section and the user (6), the thigh (5) and shank (8) Velcro attachment straps, and the two screws (7) used to increase the force on the lateral knee.
The proposed brace consists of two rigid sections, under which is compressing padding (Figure 4.2, 6), that attach to the thigh (Figure 4.2, 1) and shank (Figure 4.2, 4) of the user. These brace sections are connected by a joint (Figure 4.2, 3), which allows the user to flex and extend their knee. Two screws are located on this joint (Figure 4.2, 7), that when turned, increase the force applied to the lateral knee by moving the compressive padding (Figure 4.2, 2) between the user and the brace in the medial direction (same mechanism as H1). The brace is attached to the user using two Velcro straps, one located on the shank, and one located on the thigh. The shank strap (Figure 4.2, 8) attaches from the distal medial shank section to the proximal lateral shank section, around the posterior side of the user. The thigh strap (Figure 4.2, 5) attaches from the proximal medial thigh section to the distal lateral thigh section, again on the posterior side of the user.

This brace design could prove advantageous with regards to effective brace length, primarily due to the location and orientation of the Velcro straps, and the rigid thigh and shank brace sections. These components were designed to reduce the pressure applied to the lateral side of the user, while increasing the distance between the knee and the pressures applied on the medial side. When the force applied to the lateral knee is increased using the adjustment screws, this load is axially transferred through the brace sections, with the majority of the load transmitted to the medial side. Furthermore, as the medial contact with the user is relatively small on the shank and thigh sections, this load is primary located at the furthest distance from the knee joint, achieving an effective brace length comparable to the geometric brace length.
Although these modifications appear small, they could significantly improve brace effectiveness. Assuming this design adopts the brace length of the dual hinged brace analysed in this study (thigh section = 0.20 m, shank section = 0.175 m), and that the design modifications proposed result in a geometric brace length equal to the effective brace length, clinically significant load reductions (4.5 Nm) could be achieved with a 33 % decreased in lateral load (75 N versus 50 N). Alternatively, using the same assumptions, and the mean lateral load measured for the dual-hinged brace experimentally (75 N), the proposed brace could apply a brace moment close to 7 Nm, which is over twice as large as the mean brace moment computed for H1.

Trends in the pressure distributions made it possible to identify brace components that reduced the effective brace length. For both braces, two components were identified, being the lateral and medial rigid portions of the thigh section of the braces. These components were modified in a new proposed design, possibly resulting in a geometric brace length comparable to the effective brace length. If so, the proposed brace could apply a more substantial brace moment, compared to the braces analysed in this study, with the same amount of force applied to the lateral knee, thus improving brace effectiveness. Ultimately, the data from the pressure mats made it possible to suggest design improvements, making them a valuable when analyzing the function of unloader braces.

4.4 Conclusions and future work

Unloader braces are a non-invasive treatment for medial knee osteoarthritis, and literature shows that their use can reduce pain and improve function in the affected knee (Brouwer et
al., 2006). Despite these positive attributes, they have not been widely adopted in the osteoarthritic population.

The objective of this study was to develop an experimental protocol and analytical method for evaluating the mechanics of unloader braces in the context of the pressure distributions between the brace and the user, and the force and moment applied to the knee joint. To evaluate the sensitivity of the technique, two distinct brace designs were compared experimentally. The results revealed statistically significant differences in brace mechanics, which were linked to specific design features of each brace.

This information was applied to a new conceptual brace design with the overall objective of achieving an effective brace length more comparable to the geometric brace length. If one hypothesizes that the non-compliance of patients to wear a knee brace is partly due to discomfort, this new design would be beneficial because a brace moment consistent with the affective moment of existing braces could be obtained while applying less pressure to the leg of the user.

To our knowledge, no previous studies have quantified the comfort of unloader braces, either qualitatively or quantitatively. Therefore, future work includes developing a method to assess the comfort of unloader braces compared to their effectiveness. This method could define comfort metrics based on pressure distribution, and mechanical effectiveness based on the applied brace moment. This would enable brace manufacturers to improve
the comfort of their designs, and potentially increase the suitability of unloader braces as a non-invasive treatment for osteoarthritis.
References


Brandon S., Deluzio K.. Robust Features of Knee Osteoarthritis in Joint Moments are Independent of Reference Frame Selection. Clinical Biomechanics. 2011:26(1);65-70


Appendices

Appendix A: Sample procedures

This study used several techniques to compute the reported results. This section outlines the procedure used for cross-correlation and filtering, both of which were important in the analysis performed.

A.1: Filtering

All data in this experiment were filtered using a dual pass 2nd order Butterworth filter in Matlab, with a 6 Hz cut-off frequency, to remove noise from the measured signals. Sample data from one subject, showing the filtered (Figure A.1, Red) and original data (Figure A.1, Green) is shown for the data measured from the lateral force transducer for an entire gait cycle. Here the filtered signal shows a substantial decrease in noise, while maintaining a shape similar to the original signal. The largest difference between the two signals occurred during a portion of the gait cycle that was not used in the analysis (Figure A.1, Frame 525).
Figure A.1: Filtering example, showing original lateral force signal (Green) and the filtered signal (Red)
A.2 Cross-correlation

In order to synchronise the data collected from the pressure mats to the rest of the system, cross-correlation was used. At the beginning of the trial, the subject was instructed to press on the lateral pressure mat, under which a load cell was placed. This resulted in peaks in the pressure mat data and in the load cell data. Peak pressure mat data (Figure A.2, Top, Red) and the load cell data (Figure A.2, Top, Green), were used as inputs into the cross-correlation code. The result of this code was a lag between the two input signals. This lag was used to either add zeros or truncate the beginning of the pressure mat data signal, resulting in synchronisation between the pressure mat data and the data from the rest of the system (Figure A.2, Bottom). The addition of zeros at the beginning of the trial did not affect results as the last three gait strides during the trial were used in the analysis.
Figure A.2: Cross-correlation example, showing peak lateral pressure (Red) and lateral synch signal (Green) before (Top) and after the lag between signals was removed using cross-correlation (Bottom)
Appendix B: Data for all subjects

Due to the size of the data set, a single representative subject was reported in Chapter 3 for thigh lever arm, lateral load at the knee, brace deflection, brace moment, as well as brace stiffness. This section shows the results from all five subjects that were analysed for H1 (Figure B.1), and H2 (Figure B.2).
Figure B.1: Thigh reaction distance (A), lateral load (B), brace deflection (C), brace moment (D), and brace stiffness (E) for all subjects for H1 as a percentage of stance phase, showing mean waveforms +/- 1 standard deviation.
Figure B.2: Thigh reaction distance (A), lateral load (B), brace deflection (C), brace moment (D), and brace stiffness (E) for all subjects for H2 as a percentage of stance phase, showing mean waveforms +/- 1 standard deviation.
Appendix C: Pilot study data

As the experimental setup was limited to two pressure mats, the shank lever arm was estimated based on pilot testing data. This section highlights key results from this testing, showing the shank lever arm distances for H2 (Figure C.1, Top) and H1 (Figure C.1, Bottom), calculated for two subjects using the last three strides of a walking trial, showing the raw results as well as the mean values for both braces.
**Figure C.1**: Shank lever arm for H2 (Top) and H1 (Bottom), showing the raw results for two subjects as a percentage of stance phase for three strides, as well as the mean values for both braces shown at mid-stance.
Appendix D: Coordinate system transformation and validation

In order to compute the thigh lever arm, the data measured using the medial and lateral pressure mats were converted to the thigh coordinate system. This process began with the definition of five segments in Visual3D:

1. Lab
2. Thigh brace section
3. Shank brace section
4. Medial pressure mat
5. Lateral pressure mat

Two joint angles were computed using these segments, following the X-Y-Z rotation sequence:

1) Between the medial pressure mat segment and the thigh brace segment
2) Between the lateral pressure mat segment and the thigh brace segment

The origin of the medial and lateral pressure mat coordinate systems were expressed in the thigh coordinate system again using Visual3D, and exported with the joint two joint angles defined above.

Two geometric arrays were constructed in Matlab using the geometry of the pressure mats, representing the position of the center of each pressure mat cell, for the lateral and medial pressure mats. These arrays used the same coordinate systems as those defined in Visual3D for the medial and lateral pressure mats.
Figure D.1: Schematic of pressure mat, showing geometry, coordinate system definition, location of origin (Red dot), center of the individual cells (Blue dots), and the position of the center of each cell with respect to the origin (Right)

Using the joint angles between the pressure mat coordinate systems and the thigh segment, the pressure mat position arrays ($\vec{P}_p$) were converted into the thigh frame using the rotation matrix ($\vec{R}_{p \to \text{Thigh}}$), again adopting X-Y-Z (flexion-adduction-internal rotation) as the rotation sequence, and the position of the coordinate system origin.
\( \vec{P}_{PO(Thigh)} \) expressed in the thigh frame (Equations D.1). This process was performed twice, once for the medial pressure mat, and once for the lateral pressure mat.

\[
\vec{P}_{Thigh} = \vec{P}_{PO(Thigh)} + \vec{R}_{P\rightarrow Thigh} \ast \vec{P}_p
\]

(D.1)

where:

\( \vec{P}_{Thigh} \) — Position of each pressure mat cell, expressed in the thigh coordinate system

\( \vec{P}_{PO(Thigh)} \) — Position of the pressure mat origin, expressed in the thigh coordinate system

\( \vec{R}_{P\rightarrow LAB} \) — Rotation matrix between the pressure mat segment and the thigh segment

\[
\vec{R}_z = \begin{bmatrix}
\cos(z) & \sin(z) & 0 \\
\-\sin(z) & \cos(z) & 0 \\
0 & 0 & 1 \\
\end{bmatrix}
\]

and:

\( x \) — angle between the x coordinates of the pressure mat and the thigh segment

\( y \) — angle between the y coordinates of the pressure mat and the thigh segment

\( z \) — angle between the z coordinates of the pressure mat and the thigh segment

To verify the accuracy of this process, four pressure mat cell locations (Figure D.1, D, H, L, P) were constructed in Visual3D as landmarks, originally resolved in the lateral pressure mat coordinate system. They were converted to the thigh coordinate system using the “Transform_Data_Coordinate_System” pipeline command. The results from the Matlab process and the Visual3D solution are shown in Table D.1. This validation shows that Matlab and Visual3D produce equivalent solutions. Small differences are expected, considering that the results in Matlab were filtered prior to this analysis.
Table D.1: Position of four pressure mat cells (Figure D.1, D, H, L, P), expressed in the thigh coordinate system, at a single frame, computed using the process described in this section, as well as using a Visual3D command, with values expressed in cm.

<table>
<thead>
<tr>
<th>Coordinate</th>
<th>Point D</th>
<th>Point H</th>
<th>Point L</th>
<th>Point P</th>
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<td>V3D</td>
<td>Matlab</td>
<td>V3D</td>
<td>Matlab</td>
</tr>
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<td>1.59</td>
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<td>1.29</td>
</tr>
<tr>
<td>Y</td>
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<td>-4.61</td>
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<tr>
<td>Z</td>
<td>24.76</td>
<td>24.73</td>
<td>23.44</td>
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</table>
Appendix E: Ethics board approval

QUEEN’S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD-DELEGATED REVIEW
July 16, 2013

Dr. Kevin Deluzio
Department of Mechanical and Materials Engineering
Queen’s University

Dear Dr. Deluzio

Study Title: MECH-047-13 Effectiveness of Knee Unloader Bracing To Reduce Medial Knee Contact Force During Gait.
File # 6010273
Co-Investigators: Dr. A. Campbell, Mr. S. Brandon, Mrs. A. Morton, Mr. M. Brown

I am writing to acknowledge receipt of your recent ethics submission. We have examined the protocol, peer review, WOMAC questionnaire, recruitment letter, revised information/consent form – controls and revised information/consent form – osteoarthritis participants for your project (as stated above) and consider it to be ethically acceptable. This approval is valid for one year from the date of the Chair's signature below. This approval will be reported to the Research Ethics Board. Please attend carefully to the following listing of ethics requirements you must fulfill over the course of your study:

**Reporting of Amendments**: If there are any changes to your study (e.g. consent, protocol, study procedures, etc.), you must submit an amendment to the Research Ethics Board for approval. Please use event form: HSREB Multi-Use Amendment/Full Board Renewal Form associated with your post review file # 6010273 in your Researcher Portal (https://eservices.queensu.ca/romeo_researcher/)

**Reporting of Serious Adverse Events**: Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information. Serious Adverse Event forms are located with your post-review file 6010273 in your Researcher Portal (https://eservices.queensu.ca/romeo_researcher/)

**Reporting of Complaints**: Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of becoming aware of the complaint. Note: All documents supplied to participants must have the contact information for the Research Ethics Board.

**Annual Renewal**: Prior to the expiration of your approval (which is one year from the date of the Chair's signature below), you will be reminded to submit your renewal form along with any new changes or amendments you wish to make to your study. If there have been no major changes to your protocol, your approval may be renewed for another year.

Yours sincerely,

Albert J. Clark
Chair, Research Ethics Board
July 16, 2013

Investigators please note that if your trial is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete
QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD

The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards and operates in compliance with the Tri-Council Policy Statement; Part C Division 5 of the Food and Drug Regulations, OHRP, and U.S DHHS Code of Federal Regulations Title 45, Part 46 and carries out its functions in a manner consistent with Good Clinical Practices.

Federalwide Assurance Number: #FWA00004184, #IRB00001173

Current 2013 membership of the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board:

Dr. A.F. Clark, Emeritus Professor, Department of Biomedical and Molecular Sciences, Queen's University (Chair)

Dr. H. Abdollah, Professor, Department of Medicine, Queen's University

Dr. R. Brison, Professor, Department of Emergency Medicine, Queen's University

Dr. C. Cline, Assistant Professor, Department of Medicine, Director, Office of Bioethics, Queen's University, Clinical Ethicist, Kingston General Hospital

Dr. M. Evans, Community Member

Ms. J. Hudacin, Community Member

Dr. B. Kisilevsky, Professor, School of Nursing, Departments of Psychology and Obstetrics and Gynaecology, Queen's University

Dr. J. MacKenzie, Pediatric Geneticist, Department of Paediatrics, Queen's University

Mr. D. McNaughton, Community Member

Ms. P. Newman, Pharmacist, Clinical Care Specialist and Clinical Lead, Quality and Safety, Pharmacy Services, Kingston General Hospital

Ms. S. Rohland, Privacy Officer, ICES-Queen's Health Services Research Facility, Research Associate, Division of Cancer Care and Epidemiology, Queen's Cancer Research Institute

Dr. A. Singh, Professor, Department of Psychiatry, Queen's University

Ms. K. Weisbaum, LL.B. and Adjunct Instructor, Department of Family Medicine (Bioethics)
QUEEN'S UNIVERSITY HEALTH SCIENCES AND AFFILIATED TEACHING HOSPITALS
RESEARCH ETHICS BOARD ANNUAL RENEWAL

Queen's University, in accordance with the "Tri-Council Policy Statement 2, 2010" prepared by the Interagency Advisory Panel on Research Ethics for the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada requires that research projects involving human participants be reviewed annually to determine their acceptability on ethical grounds.

A Research Ethics Board composed of:

Dr. A.F. Clark, Emeritus Professor, Department of Biomedical and Molecular Sciences, Queen's University (Chair)
Dr. H. Abdollah, Professor, Department of Medicine, Queen's University
Dr. C. Cline, Assistant Professor, Department of Medicine, Director, Office of Bioethics, Queen's University, Clinical Ethicist, Kingston General Hospital
Dr. R. Brison, Professor, Department of Emergency Medicine, Queen's University
Dr. M. Evans, Community Member
Ms. J. Hudacin, Community Member
Mr. D. McNaughton, Community Member
Ms. S. Rohland, Privacy Officer, ICES-Queen's Health Services Research Facility, Research Associate, Division of Cancer Care and Epidemiology, Queen's Cancer Research Institute
Dr. M. Sawhney, Assistant Professor, School of Nursing, Queen's University
Dr. A. Singh, Professor, Department of Psychiatry, Queen's University
Dr. J. Walia, Assistant Professor and Clinical Geneticist, Department of Paediatrics, Queen's University and Kingston General Hospital
Ms. K. Weisbaum, LL.B. and Adjunct Instructor, Department of Family Medicine (Bioethics)

has reviewed the request for renewal of Research Ethics Board approval for the project “Effectiveness of Knee Unloader Bracing To Reduce Medial Knee Contact Force During Gait.” as proposed by Dr. K. Deluzio of the Department of Mechanical and Materials Engineering, at Queen's University. The approval is renewed for one year, effective July 16, 2014. If there are any further amendments or changes to the protocol affecting the participants in this study, it is the responsibility of the principal investigator to notify the Research Ethics Board. Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other adverse events must be reported within 15 days after becoming aware of the information.

__________________________
Date: July 03, 2014

Chair, Health Sciences Research Ethics Board

Renewal 1[x] Renewal 2 [ ] Extension [ ] Code# MECH-047-13 Romeo file# 6010273