A Simple Method for Measuring the Changeable Mechanical Action of Unloader Knee Braces for Osteoarthritis

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Highlights

- A method for measuring the dynamic action of unloader knee braces was necessary.
- Results demonstrated the acceptable reliability of the proposed method.
- An application is provided through the orthosis moment calculation.

Graphical abstract

How to quantify the valgus orthosis moment in knee osteoarthritis?

Abstract

Purpose: Today’s orthotics should be designed to apply the external orthosis moment to the knee joint solely during the stance phase instead of the entire gait cycle. The aim of this study was to validate the reliability of a simple device for measuring forces at the leg–orthosis interface and describe the behavior of an innovating dynamic unloader knee brace built to interrupt its mechanical action during large knee flexion (swing phase of gait).

Methods: A compression testing machine was used to apply known (standard) forces to the device (modeled forces) and the results were compared.

Results: The low absolute mean bias (~4%), the narrow agreement limits associated with the Bland and Altman analysis as well as the significant linear correlation (r = 0.99; p < 0.001) validate the agreement between standard and modeled forces. Likewise, the low standard error of measurement between trials (~1.3%) and the intraclass correlation coefficient (1.00) reflect high test-retest reliability.

Conclusion: These results demonstrate the validity of the proposed device for measuring constraints induced by the dynamic unloader knee brace. An example of an application is provided through an orthosis moment calculation using kinematic data, which reveal a changeable mechanical action, necessary to improve comfort resulting in potentially better compliance.

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Keywords: Changeable orthosis moment; Knee osteoarthritis; Biomechanical intervention; Unloader knee brace
1. Introduction

Management of knee osteoarthritis (OA) is an important issue for healthcare professionals worldwide. Nonpharmacological approaches now predominate the most recent guidelines for the nonsurgical treatment of knee OA [1]. Biomechanical intervention, and particularly unloader knee braces, are being considered [2–7]. Despite differences in the mechanisms embedded in the orthoses, all interventions aim at reducing the load in the diseased knee compartment.

During the stance phase of gait, humans are submitted to an external knee adduction moment (EKAM), which leads to an increased load in the medial knee compartment [8–11]. To help the structures encompassing the joint overcome this constraint, many unloader braces have been conceived to apply an opposite external abduction or valgus moment to the knee in order to redistribute load from the medial to the lateral compartment [4].

Over the last few years, engineers have attempted to improve patient satisfaction, providing better comfort and fitting despite the mechanical action of three-point pressure [12]. Along these lines, considering the EKAM curve over the entire gait cycle is crucial, because this measurement is essential to highlight how medical devices can fit patients’ needs. Up-to-date dynamic knee braces have been conceived to produce a changeable valgus moment in order to obtain a mechanical effect (three-point pressure) solely during knee extension (stance phase) and to be inactive during knee flexion (swing phase).

To our knowledge, two studies have measured the valgus orthosis moment during walking and running [13,14]. Even though based on specific testing methods, these two studies both used strain gauges to highlight the role played by different valgus adjustments (unchangeable orthosis moment) on the knee load during walking. It was shown that the greater the amount of correction achieved by the brace, the greater the amount of unloading in the affected compartment. Unfortunately, both methods were expensive, uneasy to reproduce and required orthoses modifications.

Thus, the aim of the current study was to validate an experimental method for assessing the in situ behavior of a new dynamic knee OA brace. An inexpensive, simply to use and reliable method without any orthosis modification is proposed based on a simple homemade device incorporated into the brace, which measures horizontal forces at the leg–orthosis interface in the frontal plane. An example is then provided of a changeable valgus moment produced by this new unloader orthosis built to exert a mechanical action solely during the stance phase of gait. A brief report of this study has been previously published in abstract form [12].

2. Material and methods

2.1. Instrumented device and sensor calibration process

As shown in Fig. 1, the device, which measures forces medially in the lower segment of the brace, is composed of two sensors (Interlink FSR-402 short model) separated by 6 cm, each covered by discs on their working surfaces (13 mm diameter) and encompassed by two metal bars (aluminum). The device is 8 mm thick and 13 cm long.

For this study, it was assumed that the force applied on the device was equal to the sum of the forces delivered by each sensor. Each sensor was calibrated over its complete range with a compression testing machine (Hounsfield S-series) combined with a LabVIEW interface (homemade routine) sampled at 1000 Hz (National Instruments, USB-6009). The compression testing machine applied known forces from 5 to 90 N on the discs at a low speed of 1 mm · min⁻¹.

2.2. Device validity

After each sensor calibration, known forces were applied by the compression testing machine on the upper bar of the device. The two calibrated sensors were summed (modeled values) and compared to the forces exerted by the machine (standard values). This procedure was repeated over 3 days to obtain both the accuracy and the test-retest reliability of the device.

Accuracy was expressed through the relative absolute mean bias (%):

$$\frac{1}{n} \sum_{i=1}^{n} \left( \frac{\text{abs}(\text{standard value}(i) - \text{modeled value}(i))}{\text{standard value}(i)} \times 100 \right)$$

Compared to the mean bias (change in the mean between the standard and modeled values) in which a value close to zero may result from compensation between positive and negative differences, a relative absolute mean bias presents the advantage of better expressing the bias.

In addition to the relative absolute mean bias, the Bland and Altman analysis [15] is another and complementary statistical analysis used to assess the accuracy of modeled forces. This analysis quantifies the agreement between two quantitative measurements by constructing limits of agreement [16]. These
statistical limits are calculated using the mean and the standard deviation (SD) of the differences between standard and modeled values if they are normally distributed (bias ± 1.96 · SD), as represented in Fig. 2d. With this analysis, 95% of the errors between the standard and modeled forces should be included within this agreement range. Thus, the lower the bias and the narrower the limits of agreement, the higher the agreement between the standard and modeled values.

Finally, test-retest reliability can be assessed through the standard error of measurement (SEM), [17], which is directly interpretable in the unit of measurement [18]. It represents the variation that can be observed across repeated similar trials. The following expression [17] was used to calculate the SEM:

$$SEM(\%) = \frac{SD_{diff}}{\bar{X}} \times \sqrt{2} \times 100$$

with \(SD_{diff}\) and \(\bar{X}\) corresponding to the standard deviation of the differences between the trials conducted at 3-day intervals and the mean of the overall values (trial 1 + trial 2), respectively. To complete the SEM, the intraclass correlation coefficient (ICC) is another quantitative assessment of the test-retest reliability [18].

The significance level adopted in this study was \(p < 0.05\) and the statistical calculations were carried out using Statistica (StatSoft Inc., version 8.0).
2.3. Orthosis moment calculation

The dynamic orthosis (Alteor, France) used in this study was composed of aluminum hinges, thigh and calf polypropylene shells and comfortable foam. This orthosis was built to be fully activated, i.e., exert a three-point pressure action during knee extension (stance phase of gait) and inactivated during large knee flexion (swing phase of gait). Embedding the device (sampled at 560 Hz) in the medial hinge of the valgus brace and positioning retro-reflective markers at the sensor levels allow the calculation of lever arms between force sensors and the knee joint center (KJC) defined as the midpoint between the medial and lateral femoral epicondyles, as shown in Figs. 3 and 4. Kinematic data (BTS, SMART-D, Italy) synchronized with the device were collected with a 12-infrared camera system at 140 Hz.

2.4. Procedure

To provide an example magnifying the size of the changeable orthosis moment, a subject with a 45-mm intercondylar distance [19] with varus knee deformity was chosen. This subject (height, 1.80 m; mass, 75 kg; age, 24 years) was instructed to walk over a 10-m laboratory walkway at a self-selected speed with the dynamic unloader knee OA brace. Before fitting the brace, two markers were attached to the skin over the medial and lateral femoral epicondyles and three noncolinear markers were placed on the upper thigh. A preliminary static loading test was performed to locate the KJC in relation to the three upper thigh markers. After removing the two knee markers, the brace was fitted to the subject and a second preliminary record in static knee flexion (inactivated brace) was performed to obtain the tightening force of the brace, which corresponds to the device’s compression between the leg and the orthosis due to strap tension. Then, during the gait trial, the KJC was estimated with the remaining thigh markers. Kinetic and kinematic data were low-pass filtered using a fourth-order recursive Butterworth filter with a 10-Hz cut-off frequency.

The entire procedure was carried out in accordance with the Declaration of Helsinki and the subject was given an explanation of the study and provided written informed consent.

3. Results

The device looks imperfect since modeled forces before correction did not fit standard forces, as expressed by the equation of the linear regression represented in Fig. 2a and Table 1. The sum of the two calibrated sensors (dotted line) was indeed too high compared to the standard forces (solid line) applied by the compression testing machine. In addition, it can be seen that the gap tends to increase as the exerted load itself increases. Therefore, accuracy was not satisfactory and Fig. 2a shows proportional errors that have to be corrected by linear regression (Fig. 2b) as follows:

modeled forces (after correction) = x – (0.3264x – 3.4576)

with x the modeled value before correction, 0.3264 and 3.4576 the slope and y-intercept values, respectively.

After correction (Fig. 2c), the mean bias and the relative absolute mean bias were approximately equal to 0 and 4%, respectively (Table 1). Moreover, the Bland and Altman plot (Fig. 2d) shows a narrow agreement range [−2.2 N; +2.2 N] inferring low errors between the standard and modeled values. Note that these errors were normally distributed (Shapiro–Wilk test, p < 0.68). The results show a strong significant linear correlation between the standard and modeled values (r = 0.99; p < 0.001) (Fig. 2c). Finally, the test-retest reliability (SEM) for the device (Fig. 2e) was close to 1.3% (Table 1) and the ICC was equal to 1.00 (confidence limits: 0.99; 1.00).

Fig. 5 displays the time course of the changeable orthosis moment calculated at the knee. Approximately, at the onset of the swing phase (~60% of gait cycle), the orthosis moment falls close to zero, resulting in an inactivated device (large knee flexion). In the first moments of the stance phase of gait, the orthosis does not exert a fully valgus moment to the knee due to a small knee flexion after foot contact.

4. Discussion

This study aimed at validating a simple method for measuring the dynamic activity of unloader knee braces for OA.
Considering the development of braces with a changeable valgus moment to potentially improve compliance, describing and measuring the mechanical effects of this type of orthosis was necessary. More specifically, the study applied solely a mechanical action during the stance phase of gait (knee extension). Therefore, a device embedded in the brace that measures forces at the leg–orthosis interface was used to fulfill this requirement. To our knowledge, this study is the first to provide a simply to use method allowing to quantify a changeable valgus orthosis moment over the gait cycle.

The statistical analysis demonstrates the high validity of the device, as shown by both accuracy and test-retest reliability indices. Accuracy close to 4% between the standard and modeled values is fully acceptable in this context, with a maximum error less than 2 N (Table 1). Likewise, as seen in the Bland and Altman chart (Fig. 2d), the mean bias is equal to zero and the limits of agreements are narrow [±2.2 N]. This result indicates that 95% of the errors between the standard and modeled values should come within this short range. Moreover, the linear regression ($r^2 = 0.99$; $p < 0.001$; Fig. 2e) also demonstrates high accuracy. The test-retest reliability (Fig. 2e), with a SEM and an ICC equals to 1.3% and 1.00, respectively, is also worth noting. Therefore, taken together, these statistical data reflect the validity for measuring the forces applied on the device.

However, as described in the Results section, a posteriori correction of the modeled forces is a prerequisite to obtain this agreement. The need for the correction could be explained by the simplicity of the approach, where modeled values result from the sum of the two calibrated sensors that could lose or gain force in all the device’s parts described in Fig. 1. For example, the deformity caused by the device at the highest exerted forces was not taken into account. This simplicity leads to errors proportional to the applied force: the greater the force, the larger the error (Fig. 2a). A simple correction with a linear regression (Fig. 2b) can be useful to obtain fitted data compared to the identity line (Fig. 2c). Therefore, according to this explained correction, all researchers have the tools for reproducing accurately this new proposed approach.

Naturally, obtaining an external orthosis moment to quantify the mechanical effect produced by the orthosis should be preferred (Figs. 4 and 5). The orthosis moment highlights the contribution of the brace to help knee joint and soft tissues counteract the EKAM. Interestingly, some authors have already described this measurement with an unchangeable orthosis mo-

![Fig. 4. Orthosis moment = $\vec{f}_1 \times d_1 + \vec{f}_2 \times d_2$ with $\vec{f}_1$ and $\vec{f}_2$ the forces at each sensor embedded in the device and $d_1$ and $d_2$ the lever arms between the knee joint center (KJC) and the sensors.](image)

<table>
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<th>Forces (N)</th>
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<th>Modeled forces (after correction) trial 1 $y = x - (0.3264x - 3.4576)$</th>
<th>Absolute bias (%)</th>
<th>Modeled forces (after correction) trial 2</th>
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ment [13,14]. In these studies, even though the EKAM was not significantly reduced for the lowest orthosis constraints, the orthosis moment was subtracted from the EKAM to obtain net EKAM values, which varied significantly. It was suggested that a valgus orthosis could counteract the EKAM and therefore help the knee joint and soft tissues, which normally sustained the external varus load alone. Thus, calculating a net EKAM using the orthosis moment should be preferred when evaluating knee moments in the frontal plane, implying that this measurement could better represent the medial knee load than the EKAM alone [13,14].

An example of a changeable orthosis moment as a function of gait cycle obtained with the current dynamic three-point pressure brace is illustrated in Fig. 5. The magnitude displayed is in accordance with previous published data based on similar measurements [13,14]. In fact, Pollo et al. [14] reported a 5.9 to 11 N m range for the orthosis moment depending on the orthosis adjustment. Similarly, Fantini-Pagani et al. [13] reported orthosis moments from 0.03 to 0.102 N m/kg. Looking at their 74.3 kg mean body mass, the orthosis moment ranged from 2.2 to 7.6 N m. Given the reported values compared to those found here in Fig. 5, the proposed method appears to be satisfactory to compute the external knee orthosis moment.

It should be pointed out that during knee flexion the brace is theoretically inactive, as described in the Methods section, and unable to exert any force. Since the knee OA brace must be tightened (strap tension), compression of the device between the leg and the orthosis is present and likely alters the recorded forces (offset). To estimate this offset, a preliminary recording in static knee flexion (inactive orthosis) to measure the tightening force should be taken into account and subtracted from the measured forces during gait (Fig. 5). Moreover, this offset determination also removes the compression of the device between the leg and the orthosis due to its thickness. As detailed in Section 2.1, the thickness of the embedded device was lower than one centimeter. Reasonably, this value procures no discomfort nor any brace alteration performance.

Finally, it is worth noting that the validity of the homemade device has been based solely on force measurement and not torque. In fact, a true calculation of an orthosis moment involves a level arm determination through kinematic data (Fig. 4). As a result, since the device’s (force measurements) reliability has been positively demonstrated in this study, kinematic accuracy could be viewed as a limiting factor in this kind of calculation. Naturally, the knee joint center determination affects the lever arms (Fig. 4). In this study, knee joint center position was determined as the midpoint between the medial and lateral femoral epicondyles. Because of its non-invasive nature, an erroneous position can be used. However, this knee joint center determination appears to be commonly adopted with the use of the current reliable motion capture systems.

5. Conclusion

The reliability for measuring the dynamic behavior of an unloader knee brace for OA with three-point pressure was assessed. Combined with traditional kinematic and kinetic gait analyses, orthosis moments can be extrapolated, thus improving our knowledge of these braces. Based on these elements, the biomechanical effectiveness of innovative dynamic unloader knee braces for osteoarthritis with different physical characteristics should be compared.

Conflict of interest statement

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