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Original Article

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

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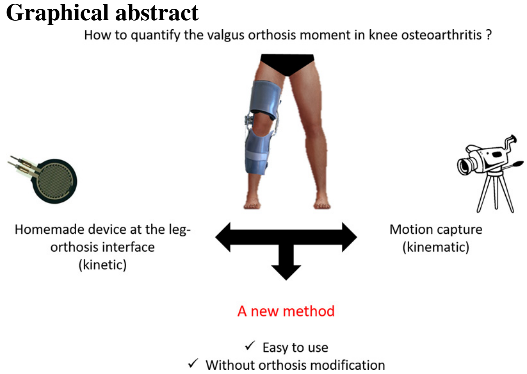
Highlights

- 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



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.

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

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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 FSR402short 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.

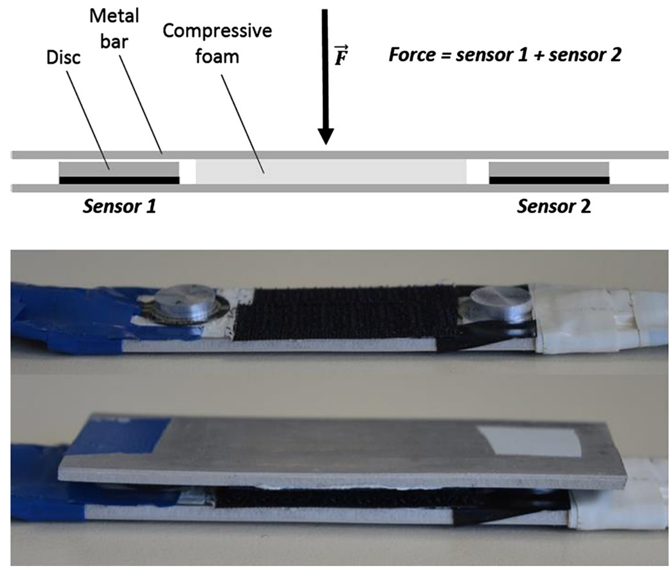

Fig. 1. Description of the device. The sum of the two force sensors is equal to the force applied on the upper metal bar. This device should be placed in the lower segment and medially at the leg–orthosis interface.

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 (%):

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

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