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Short communication

Validation of method for analysing mechanics of unloader brace for medial knee osteoarthritis

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ABSTRACT

Unloader braces are one non-invasive treatment of knee osteoarthritis, which primarily function by applying an external abduction moment to the joint to reduce loads in the medial compartment of the knee. We developed a novel method using brace deflection to estimate the mechanical effect of valgus braces and validated this model using strain gauge instrumentation.

Three subjects performed static and walking trials, in which the moment applied by an instrumented brace was calculated using the deflection and strain methods. The deflection method predicted average brace moments of 8.7 Nm across static trials; mean error between the deflection model predictions and the gold-standard strain gauge measurements was 0.32 Nm. Mean brace moment predictions throughout gait ranged from 7.1 to 8.7 Nm using the deflection model. Maximum differences (MAE) over the gait cycle in mean and peak brace moments between methods were 1.50 Nm (0.96) and 0.60 Nm (0.42).

Our proposed method enables quantification of brace abduction moments without the use of custom instrumentation. While the deflection-based method is similar to that implemented by Schmalz et al. (2010), the proposed method isolates abduction deflection from the 3 DOF angular changes that occur within the brace. Though the model should be viewed with more caution during swing (MAE = 1.16 Nm), it was shown that the accuracy is influenced by the uncertainty in angle measurement due to cluster spacing. In conclusion, the results demonstrate that the deflection-based method developed can predict comparable brace moments to those of the previously established strain method.

1. Introduction

Osteoarthritis (OA) is the most common form of arthritis, occurring more frequently in the medial compartment of the knee (Felson, 2004). Most OA is caused, in part, by mechanically induced injury to joint tissues (Felson and Radin, 1994). Studies have shown that the external knee adduction moment, positively correlated with mechanical axis (varus alignment) (Wada et al., 2001), is greater in patients with OA versus normal populations, and that there is a moderately strong relationship between adduction moment and disease severity (Sharma et al., 1998; Foroughi et al., 2009; Mündermann et al., 2004). There is a good correlation between the knee adduction moment and medial joint loads, however, previous studies have questioned the strength of the relationship, revealing varying results (R^2 ranging from 0.57 to 0.93) (Walter et al., 2010; Zhao et al., 2007). Other biomechanical parameters, such as the knee flexion moment, have also been reported to play a role in future disease progression (Chehab et al., 2014). Commonly, however, the knee adduction moment remains to be the target of various interventions that aim to reduce joint loading and slow disease progression (Kutzner et al., 2013; Trepczynski et al., 2014).

One non-invasive treatment of knee OA is valgus bracing, which has been found to provide improvements in pain and function in patients with varus alignment (Moyer et al., 2015b; Ramsey and Russel, 2009; Lindenfeld et al., 1997). Multiple brace mechanisms for altering knee joint biomechanics have been proposed, including improving malalignment, providing a valgus brace moment to counteract the knee adduction moment, increasing joint stability, lessening muscle co-contraction, and improving proprioception (Moyer et al., 2015a; Briem and Ramsey, 2013). Kutzner et al. (2011) examined the effectiveness of unloader braces by measuring knee loading *in vivo* using instrumented implants in patients who underwent total knee replacements. Reductions in medial

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knee loads ranged from 0 to 30 percent, depending on the subject, brace design, and valgus adjustment.

Kutzner provided a strong baseline for measuring the effect of valgus braces. However, the number of subjects with instrumented knee implants is limited, and differing knee morphology makes using these results with an OA population difficult. Therefore, a need persists for the development of a method to accurately quantify the effect of braces without invasive surgery. The brace abduction moment has been previously measured using load sensors, such as pressure bladders (Self et al., 2000), or with strain gauges (Pollo et al., 2002; Fantini Pagani et al., 2010a, 2010b). Pollo et al. also used analytical models to estimate medial load reduction using valgus bracing. These methods of measuring brace moment provide accuracy, however, each of these sensing solutions requires specific instrumentation, which may alter the brace or influence subject gait patterns.

Schmalz et al. (2010) introduced a method for determining brace moment using standard optical motion capture. Optical cameras were used to measure the deflection of the brace and the brace moment was computed using a predetermined stiffness. The model calibrated the force-deflection relationship of full-leg braces in fully-extended positions using three reflective markers to measure deformation. However, it is not possible to accurately distinguish between flexion, abduction, and internal rotation using only three markers; three markers in three-dimensional (3D) space define a single angle.

The purpose of this study was to develop a novel method for non-invasively measuring the moment applied by valgus braces by creating a 3 degree-of-freedom (DOF) deflection model for the brace to isolate abduction. The secondary objective was to validate the results of this model *in vivo* using the previously established method of strain gauge instrumentation.

2. Methods

An OA Assist brace was obtained for this study (DJO Global, California). Previous studies examined the functionality of similar braces that apply an unloading moment to the knee via the principle of three-point bending (Schmalz et al., 2010; Kutzner et al., 2011; Chew et al., 2007; Richards et al., 2005) (Fig. 1A). The brace features a deformable lateral beam attached to the leg, which, in conjunction with distal and proximal straps, applies a brace abduction moment that counteracts the external knee adduction moment, reducing loads in the medial compartment of the knee. For the brace in this study, the force applied can be increased or decreased using a screw-based load adjustment mechanism in the lateral beam, which applies a medially-directed load at the lateral epicondyle (Fig. 1B).

The brace was instrumented with a half-bridge strain gauge configuration. Two 350 Ω strain gauges (FLA-2-350-17-3L, Tokyo Sokki Kenkyujo Co., Ltd., Japan) were mounted on either side of the proximal portion of the lateral beam of the brace (Fig. 1B). The half-bridge configuration allowed for the measurement of strain purely due to bending of the brace. This rejected strain due to axial and torsional forces, which was verified experimentally. The output from the gauge configuration was measured using an auto-balanced Model P3 Strain Indicator with a bridge excitation of 1.5 V (Micro-Measurements, Raleigh, North Carolina).

To calibrate brace moment to deflection and strain, the effect of the brace on a subject was replicated in a controlled environment using a custom mechanical rig (Brandon, 2015). The apparatus consisted of two sections of acrylonitrile butadiene styrene (ABS) pipe covered in layers of ethylene vinyl acetate (EVA) foam, representing thigh and shank segments. These pipes were rigidly connected to two plywood frames, which were bolted to two 6 DOF load cells (force platforms) (AMTI, Watertown, MA, USA). (Fig. 2).

The brace was strapped to the apparatus, with the thigh and shank sections tightened around the EVA foam. Based on previously recorded moments for other braces, a minimum induced brace moment of 10 Nm was desired during calibration (Gaasbeek et al., 2007; Pollo et al., 2002). Four calibration trials were performed while manually applying a vertical load up to 100 N (Kutzner et al., 2011; Fantini Pagani et al., 2010b) to the centre of the lateral beam.

Throughout trials, the reaction forces and moments, motion capture, and strain data were captured synchronously. Ground reaction forces were sampled at 500 Hz using two force platforms (2xCustom BP model, AMTI, MA). Motion kinematics were tracked at 100 Hz by an eleven-camera motion capture system (Oqus 400, Qualisys, Gothenburg, Sweden) using reflective markers fixed to the brace. Clusters of four markers were attached at the proximal and distal ends of the lateral beam with an additional marker fixed at the brace joint centre. Analog strain data were sampled at 500 Hz using the strain indicator.

The calibration analysis involved performing a moment balance from each force platform to calculate two independent measures of

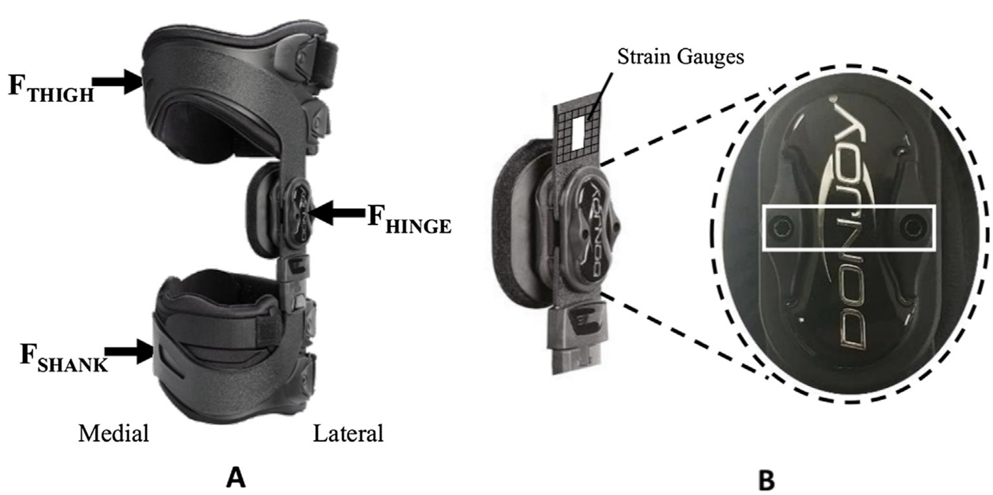

Fig. 1. (A) OA Assist brace (DJO Global, Vista, California). Equivalent three-point bending loads applied by the brace to the user from thigh, shank, and hinge elements are shown. Black arrows indicate forces applied to the subject by the brace; the force from the hinge, F_{HINGE}, and the forces from the thigh and shank sections, F_{THIGH} and F_{SHANK}. (B) Screw mechanisms (white) used to increase the force applied to the lateral knee epicondyle. Two 350 Ω strain gauges were mounted on either side of the proximal portion of the lateral beam as shown.

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