



## Biomechanical effectiveness of a distraction–rotation knee brace in medial knee osteoarthritis: Preliminary results



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### ARTICLE INFO

#### Article history:

Received 26 September 2013

Received in revised form 6 February 2014

Accepted 17 February 2014

#### Keywords:

Locomotion

Biomechanics

Knee osteoarthritis

Knee brace

### ABSTRACT

**Background:** Non-pharmacological therapies are recommended for the care of knee osteoarthritis patients. Unloader knee braces provide an interesting functional approach, which aims to modulate mechanical stress on the symptomatic joint compartment. We aimed to confirm the biomechanical effects and evaluate functional benefits of a new knee brace that combines a valgus effect with knee and tibial external rotation during gait in medial osteoarthritis patients.

**Methods:** Twenty patients with unilateral symptomatic medial knee osteoarthritis were included and they performed two test sessions of 3D gait analysis with and without the brace at the initial evaluation (W0) and after 5 weeks (W5) of wearing the brace. VAS-pain, satisfaction scores, WOMAC scores, spatio-temporal gait parameters (gait speed, stride length, stance and double stance phases, step width), and biomechanical data of the ipsilateral lower limb (hip, knee, ankle and foot progression angles) were recorded at each session.

**Results:** VAS-pain and WOMAC significantly decreased at W5. Walking speed was not significantly modified by knee bracing at W0, but increased significantly at W5. Knee adduction moments and foot progression angles significantly decreased in the terminal stance and push off, respectively, with bracing at W0 and W5. Lower-limb joint angles, moments and powers were significantly modified by wearing the brace at W0 and W5.

**Conclusion:** This new knee brace with distraction–rotation effects significantly alters knee adduction moments and foot progression angles during gait, which might lead to significant functional gait improvements and have carry-over effects on pain at the short term in osteoarthritis patients (<2 months).

**Level of Evidence:** level IV.

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## 1. Introduction

Knee osteoarthritis (OA) is a frequent chronic crippling disease with neither available curative treatments, nor therapies able to slow its natural progression. Nevertheless, its prevalence is steadily increasing in developed countries, due to the ageing of the population (12% after 65 years and 27% after 75 years), with a clear predominance of women [1–3]. The medial compartment is most frequently affected (85%), even without any misalignment in the lower limbs [4–6] and the load on this compartment increases rapidly in cases of constitutional or acquired *genu varum*. This load can be estimated indirectly by analyzing

the knee adduction moment [7–9] which correlates well with knee pain and joint space narrowing [10–12].

An integrated approach of pharmacological and non-pharmacological therapies is recommended for the optimal care of OA patients (ACR, EULAR, OARSI [13]). Among these, valgus knee braces provide an interesting functional approach, which aims to modulate mechanical stress on the symptomatic joint compartment by diminishing the adduction moment. The biomechanical effectiveness of these functional knee braces is still controversial, as certain authors found no significant reduction in the adduction moment [14–16] or underlined other mechanisms to explain the pain relief [17] such as modifications in muscle co-contractions or improvements in proprioception. In contrast, other studies have reported decreases in the adduction moment with the use of such unloader braces [18] during biomechanical simulations [8,19] in healthy subjects (18 to 30 years old: [20–22]), or in patients with medial knee OA [23–25].

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In addition to the valgus-induced (i.e. distraction) mechanism, it is possible to reduce the adduction moment by increasing the external rotation of the ipsilateral leg and foot [26–29]. Indeed, external rotation makes it possible to shift the vertical axis of the ground reaction force vector backwards and medially toward the center of the knee joint, which reduces the knee adduction moment. In healthy subjects, the valgus alignment and the foot progression angle (angle between the axis of the foot in the axial plane and the direction of gait) are predictors of biomechanical internal femoral–tibial constraints [30]. However, in medial-compartment knee OA, there have been no studies about the biomechanical effect of an unloader knee brace, which combines distraction with rotation, to assess the potential complementary interest of this external rotation in the axial plane.

The aim of this open-label study was to quantify, using quantitative gait analysis and patients' satisfaction, the benefits of a novel unloader brace with a double function of distraction (valgus) and external rotation in patients suffering from medial compartment knee osteoarthritis.

## 2. Materials and methods

### 2.1. Participants

Patients aged 40 to 80 years old, with unilateral medial symptomatic knee OA, defined using the American College of Rheumatology criteria were included [31] in this prospective, single-center interventional study. Other inclusion criteria were knee pain at least 4/10 (VAS), and Kellgren and Lawrence stage  $\geq$  II, on the X-ray. Exclusion criteria were secondary knee OA, inflammatory knee OA, significant pain, ankle, hip or foot disorders, chronic back pain, Alzheimer's disease, Parkinson's disease, motor neuron disorders, non-stabilized diabetes mellitus, cardiac or respiratory insufficiency and inability to understand the procedure. The study protocol was approved by the local ethics committee (CPP Est I, Dijon, France) and was registered under ClinicalTrials.gov Identifier: NCT01884883. The study was conducted in compliance with the principles of Good Clinical Practice and the Declaration of Helsinki and all patients signed an informed consent form.

### 2.2. Study procedure

The subjects came to the laboratory three times. The aim of the first visit was to make a cast of each patient's lower limb in order to manufacture the custom knee brace. During the second visit, patients tried their custom-fit braces in order to make final adjustments, and then performed the initial three dimensional, 3D gait analysis (W0) in two conditions: without and with the brace, 12 walks per condition. The patients then wore the brace for at least six hours per day for five weeks without interruption. During this period, the patients were invited to note down in a diary every problem caused by wearing the brace. At the end of this five week period, the patients returned to the laboratory for a third time to perform the second and final gait analysis. The analysis was conducted in the same two conditions (with and without the brace).

### 2.3. Knee brace

PROTEOR (France) has developed an ODRA® brace (*Distraction and Rotation Orthotic Device*). This brace presents rigid femoral and tibial bands (Fig. 1a) and is custom-made from lower limb casts. The Supplementary video and Fig. 2 illustrate how the brace functions. Each hinge of the brace (upper part and lower part) is linked to a pinion rack system that slides into a slotted hole. The medial and lateral hinges move along the vertical and the horizontal axes, respectively. These movements mechanically respectively induce vertical (distraction) and horizontal (rotation) displacement of the

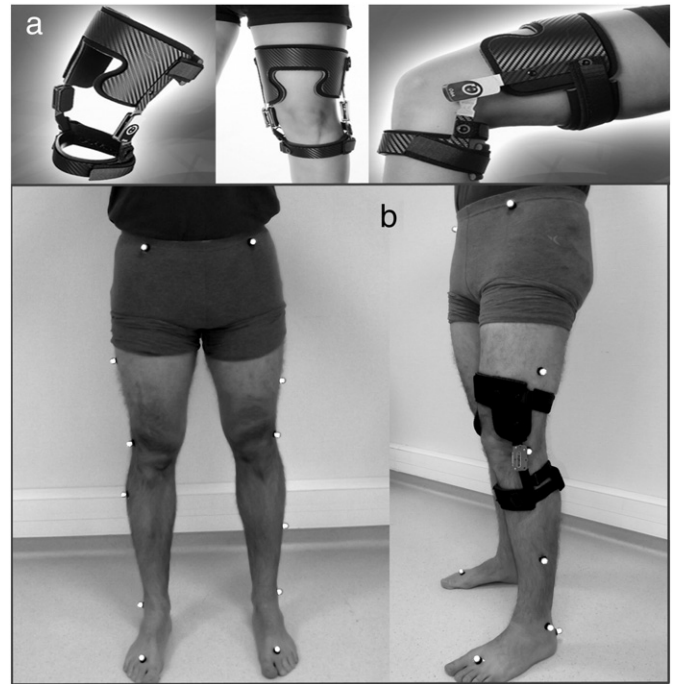


Fig. 1. (a) Pictures of the new ODRA brace. (b) Marker set adapted with ODRA brace in situ.

medial and lateral hinges that aim to reduce the load on the knee's medial compartment [29]:

- Medial distraction (valgus effect):
  - When the leg is extended in the stance phase, a medial hinge causes the orthotic device to extend, thereby creating, hypothetically, distraction between the femur and tibia.
- Lateral rotation:
  - The lateral hinge causes the joint to shift back along its midline, simultaneously resulting in an outward rotation of the foot.

It should be noted that the brace induces valgus and rotation when the knee is extended and the effect is null when the knee is flexed.



Fig. 2. Picture of the distraction-rotation mechanism of the ODRA brace.

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