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Acute effects of different orthotic interventions on knee loading parameters in knee osteoarthritis patients with varus malalignment

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ABSTRACT

Background: Knee osteoarthritis (KOA) is the most common form of arthritis with an estimated lifetime prevalence of 45%. The use of orthotic devices is a generally accepted conservative therapy in KOA. A new conservative treatment is an ankle–foot orthosis (AFO); however, studies on the biomechanical effects are limited. The aim of this study was to examine the acute effects of different orthotic devices (AFO, knee brace and wedged shoes) on (un)loading parameters in subjects with KOA.
Methods: Fifty-two medial KOA patients (mean age 59 (standard deviation (SD) 10) years and mean body mass index 27.5 (SD 4.9) kg/m^2) were recruited. Three-dimensional gait analysis was undertaken with different interventions in a randomized order: control (own shoes), new AFO, conventional unloader brace and laterally wedged shoes (six degrees).
Results: Significant decreases of 27% and nine percent in first peak knee adduction moment (KAM) were observed for the AFO and wedged shoes, respectively, in comparison with the control. Significant decreases of 21%, seven percent and 18% in the KAM impulse were observed for the AFO, brace and wedged shoes, respectively, compared to the control. The knee flexion moment (KFM) increased compared to the control for all conditions, but only significantly while using the AFO, showing an increase of 26% as compared to the control.
Conclusions: The AFO and wedged shoes were more effective in unloading the medial compartment of the knee compared to the unloader brace. However, the effect of an increased KFM on KOA remains unclear and requires further investigation.

1. Introduction

Osteoarthritis (OA) is the second most common musculoskeletal disease worldwide [1]. Knee osteoarthritis (KOA) is the most frequent form of OA with an estimated lifetime prevalence of 45% [2]. The primary symptoms of KOA include joint pain and stiffness [3]. The pathology is characterised by progressive joint destruction with cartilage loss, abnormal remodelling and erosion of subarticular bone, bone growth at the joint margins (osteophytes), ligament softness and weakening of muscle [4,5]. Incidence of KOA is strongly associated with age, together with a variety of risk factors, including obesity, lack of exercise, genetic predisposition, gender, bone density and trauma [6]. The prevalence of KOA is likely to increase due to the ageing population and the obesity epidemic in the developed western world; therefore, by the year 2020, OA is expected to be the fourth leading cause of disability worldwide [7].

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Over the past decades, several studies have demonstrated that increased knee joint loading is an important risk factor for progression of KOA [6,8]. During walking, 60–80% of the total knee load passes through the medial compartment [9], causing the medial compartment of the knee to be affected approximately 10 times more often than the lateral compartment [10]. In the frontal plane, the load-bearing axis is represented by a line that runs from the centre of the femoral head to the ankle joint centre [11]. In patients with varus malalignment, the ground reaction force (GRF) vector passes more medially to the centre of the knee, thereby further increasing the force on the medial tibiofemoral compartment [12]. The moments acting on the knee as a result of the orientation of the GRF vector are closely related to the medial compartment contact force (MCF) [13]. As it not possible to directly measure contact forces in vivo without using invasive methods, the external knee adduction moment (KAM) is usually accepted as a surrogate measure of the load in the medial compartment and, therefore, offers a potential target for treatment strategies to slow the disease progression [14]. Furthermore, previous studies have shown that the KAM correlates negatively with joint space width and positively with varus malalignment [15,16]. In a previous study, varus malalignment was proven to increase the risk of medial compartment OA progression in KOA [17].

Furthermore, the knee flexion moment (KFM), the external moment acting on the knee in the sagittal plane, also influences MCF, and consequently the risk of KOA incidence and progression [18]. In addition, both the KAM (peak and impulse) and the KFM (peak) are related to changes in cartilage thickness and are risk factors for structural OA progression over the course of two years [13,19]. Therefore, by using only the KAM as an index of knee joint loading, we may be misinterpreting effects on MCF [20]. Considering the KAM in combination with the KAM impulse and KFM should provide a more precise representation of changes in the loading of the medial compartment [21].

The objectives of KOA management are to reduce pain and inflammation, slow down the process of cartilage degradation, improve function and reduce disability [22]. Devices such as knee braces and footwear modifications have been studied extensively and have been shown to reduce pain and improve function in patients with poor alignment [23]. Valgus braces are designed to apply a valgus moment directly at the knee through a three-point bending mechanism thus counteracting the KAM to lessen the medial compartment loading in medial KOA patients [24]. Previous studies have shown that valgus braces effectively reduce the KAM [24–26]; however, the magnitude of results varies significantly (from eight percent to 20%). Nevertheless, it has been suggested that poor patient compliance obstructs the treatment effect of bracing due to discomfort associated with brace use [24,27]. Furthermore, the long-term effectiveness of unloader braces is affected by loss of compliance over time [28].

Wedged insoles work by shifting the calcaneus into a valgus position relative to the tibia, thereby shifting the knee more medially and correcting the alignment of the lower limb to a more anatomical position [29,30]. Reductions in KAM are related to the degree of wedging of the insole, however, higher inclinations are likely to cause discomfort [31], affect patient compliance and have adverse effects on the biomechanics of the other joints of the lower limb [31].

Novel devices, such as an ankle–foot orthosis (AFO), have recently been given attention and preliminary studies suggest their usefulness in the conservative treatment of KOA [32]. The AFO aims to move the centre of pressure laterally by restricting the ankle motion in the frontal plane, resulting in a reduction of the lever arm and, therefore, reducing the varus moment acting on the knee [33]. In previous studies, the AFO reduced the KAM in both healthy volunteers and KOA patients [32,34].

In 2015, a systematic review was performed on 13 studies with KOA patients treated with a valgus knee brace, a laterally wedged insole, a neutral insole, a stiffness shoe, or patients who were given no treatment. The authors' conclusion was that the optimal choice for an orthotic device remains unclear [35].

To date, there is no consensus with regard to which intervention is most favourable or which device is most suited for the needs of specific sub-groups of patients. A comparison of the most commonly used orthotic interventions with a focus on biomechanical parameters would provide valuable insight for clinical application of orthotics in KOA. Therefore, this study aimed to investigate the acute effects of different orthopaedic devices (AFO, brace and wedge shoes) on knee (un)loading parameters (KAM, KAM impulse and KFM) in varus-aligned subjects with KOA. The secondary aim was to evaluate the relationship between gait analysis parameters, health factors and patient-reported outcomes in order to provide more information about which intervention could be more favourable for a certain sub-group of patients. Finally, we aimed to evaluate the self-assessed comfort of the different orthopaedic devices.

2. Methods

The study was registered at the German Clinical Trials Registry under 'DRKS00009392' and it was approved by the local ethical committee (Ethikkommission der Ärztekammer Westfalen-Lippe, '2015–475-f-S'). The study was carried out in compliance with the Helsinki Declaration.

2.1. Study participants

The required sample size was determined a priori with a power analysis: a total sample of 65 participants was required to detect a significant effect of the different interventions on biomechanical parameters ($1 - \beta = 80\%$), based on a prior study [36]. This study compared the immediate effect of a valgus knee brace and laterally wedged insole on the KAM. The difference in KAM reductions between these two interventions was found to be 0.03 Nm/kg and was thus used for the sample size determination.

Patients were clinically diagnosed with KOA according to the American College of Rheumatology guidelines [37]. Patients had to present knee pain on most days of the preceding month and three of the following criteria: (1) age over 50 years, (2) morning stiffness of less than 30 min, (3) crepitus, (4) bony tenderness, (5) bony enlargement or (6) lack of palpable warmth [37]. Only

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