Gait & Posture 62 (2018) 297–302

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Full length article

Acute and mid-term (six-week) effects of an ankle-foot-orthosis on biomechanical parameters, clinical outcomes and physical activity in knee osteoarthritis patients with varus malalignment

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ARTICLE INFO

Keywords:
Knee osteoarthritis
Ankle-foot orthosis
Gait analysis
Physical function
Physical activity

ABSTRACT

Background: Knee osteoarthritis (KOA) is a painful disease commonly caused by high loads on the articular cartilage. Orthotic interventions aim to reduce mechanical loading, thereby alleviating pain. Traditional orthotics appear effective, but high drop-out rates have been reported over prolonged periods.
Research question: The aim of this study was to examine the effect of a novel ankle-foot orthosis (AFO) on gait parameters, physical function and activity of KOA patients.
Methods: 29 clinically diagnosed KOA patients with varus malalignment wore an AFO for 6 weeks. Prior to and after the intervention period, 3D gait analysis, physical function tests and the KOOS questionnaire were administered. Physical activity was objectively assessed with accelerometers.
Results: The AFO immediately reduced the first peak of the knee adduction moment (KAM) and the KAM impulse by 41% and 19%. The knee flexion moment (KFM) was increased by 48%. After six weeks, the first KAM peak and KAM impulse were decreased by 27% and 19% while using the AFO. The KFM was increased by 71%. Furthermore, patients completed the functional tests faster (1.4–2.6%). The KOOS scores decreased significantly. No significant differences were found in physical activity parameters.
Significance: The six-week AFO application significantly reduced the KAM. The patients' physical function appeared improved; yet these improvements were only minor and therefore arguably clinically irrelevant. The KFM appeared to be negatively affected after six weeks, as were the scores on the KOOS subscales. In summary, even though the AFO reduced the KAM and improved physical function, the clinical benefit for KOA patients with varus malalignment after the 6-week AFO application is debatable.

1. Introduction

Knee osteoarthritis (KOA) is one of the most common joint diseases in older adults, with over 250 million people affected worldwide [1]. It mainly causes joint pain, instability, stiffness and swelling which often limits patients' daily life activities and mobility significantly [2,3].

High loads on the knee joint have been identified as a main risk factor for the development and progression of KOA [3,4]. The dynamic load on the articular cartilage can be reliably predicted by the external knee adduction moment (KAM) and KAM impulse, which are measured during the stance phase of gait [5]. An increasing body of evidence has shown that a high KAM is a risk factor for the progression and severity of the disease [5–7]. Furthermore, the knee flexion moment (KFM), which is the moment acting on the knee in the sagittal plane, may increase the risk of developing or progressing KOA [6,8]. Therefore, the treatment of KOA commonly aims at reducing these moments to prevent or reduce disease progression [9].

Orthotic interventions are frequently used as conservative therapy for KOA patients aiming to correct joint malalignment and thereby reducing knee joint loading [9]. Various devices such as knee braces, insoles and wedged shoes have been shown to immediately reduce pain and improve function in KOA patients [10]. However, patients often do not adhere to commonly used orthotic devices over longer periods, due to a lack of beneficial effects or the presence of adverse side effects [9]. Therefore, the ankle-foot orthosis (AFO) was introduced as an alternative approach. It aims to adjust the centre of pressure by restricting ankle motion in the frontal plane, resulting in a reduced lever arm, thus reducing the moment acting on the knee [11]. Preliminary studies

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https://doi.org/10.1016/j.gaitpost.2018.03.034
Received 24 November 2017; Received in revised form 5 March 2018; Accepted 23 March 2018

assessed the effectiveness and offered promising results. A pilot study of 14 healthy subjects reported an immediately reduced KAM but no such effect with laterally wedged insoles [12]. Furthermore, this novel orthosis significantly reduced the first KAM peak in healthy and KOA subjects [12,13]. KOA patients also reported pain reductions after two weeks [14]. Whether reduced knee joint load will persist over a longer period remains to be determined.

Ultimately, orthotic interventions aim to slow disease progression, alleviate pain and improve physical function of KOA patients [9]. In turn, this should enable them to remain physically active and independent during daily life. This study therefore assessed the acute and mid-term biomechanical effects of an AFO intervention in KOA patients. An additional aim was to examine the effect of an AFO on KOA patients' symptoms, physical function and physical activity (PA) during daily life after a six-week wear period.

2. Methods

A single-arm trial was conducted to examine the AFO effects on biomechanical gait parameters, symptoms, physical function and physical activity of KOA patients. Baseline measurement comprised 3D gait analysis (without and with AFO), functional tests (without AFO) and a questionnaire. Prior to the baseline measurement, participants were asked to wear an activity monitor for one week. Subsequently, patients wore the AFO for six weeks, as regularly as possible. During the sixth week, patients were asked to wear the activity monitor again. After six weeks, they returned to the gait lab to repeat measurements taken at baseline (Fig. 1). The study was approved by the local ethical committee (Ethikkommission der Ärztekammer Westfalen-Lippe, '2015-475-f-S') and was registered at the German Clinical Trials Registry under 'DRKS00009392'. All participants gave their informed consent prior to study enrolment.

2.1. Participants

Eligible adults were required to have clinically diagnosed KOA according to the American College of Rheumatology guidelines [15], with knee pain on more than four days per week for more than three months. Furthermore, they needed to have varus malalignment, as the medial compartment is the most commonly affected site of the knee joint [9] and this malalignment increases the medial tibiofemoral forces. Frontal plane knee alignment was assessed with a previously validated method [16]. Two markers were placed on the tibial tuberosity and the midpoint of the talar neck in each leg. With a standardized foot position (shoulder width apart, 10° external rotation), the angle between the four markers was measured with a digital inclinometer (Bosch, Stuttgart, Germany). Only patients of at least 2° varus malalignment were included in the study [17]. If patients were diagnosed with bilateral KOA, the device was applied to the more symptomatic knee. Patients were excluded if they (1) had a knee replacement or were scheduled for surgery; (2) suffered from rheumatoid arthritis: (3) suffered from medical conditions that could affect the test performance (i.e. severe neurologic conditions, such as Parkinson's disease) or (4) had neutral alignment (between 2° and −2°) or valgus malalignment (larger than −2°) [18].

An a-priori power analysis determined the number of patients necessary for detecting significant differences between the baseline KAM and 6-week KAM. Based on published data [19], a total sample of 41 participants was needed, with a predicted effect size of 0.4 (1-β = 80%, α = 0.05).

In total, 50 patients were selected to participate in this study. Ultimately, 29 patients were included, since the remaining 21 did not adhere to the AFO and thus discontinued participation. Various explanations were given, such as lack of beneficial effects (n = 6), adverse side-effects (i.e. knee pain, which the patient thought to be due to the AFO (n = 3), discomfort whilst wearing the AFO (n = 7)) and practical issues, e.g. not able to fit the AFO within their commonly used shoes (n = 5). The included participants were 60 (± 10) years. The majority of the patients had a normal weight (n = 10) or were overweight (BMI > 25, n = 13), whereas few were classified as obese (BMI > 30, n = 6) [20]. Sixty-five percent of the participants were female and 59% suffered from bilateral KOA. Furthermore, the patients had an average malalignment of 2.8° (± 1.4°, range 2°–8°) and 52% had previously suffered a knee injury (Table 1).

2.2. Gait analysis

3D gait analysis was performed in the gait analysis lab at the

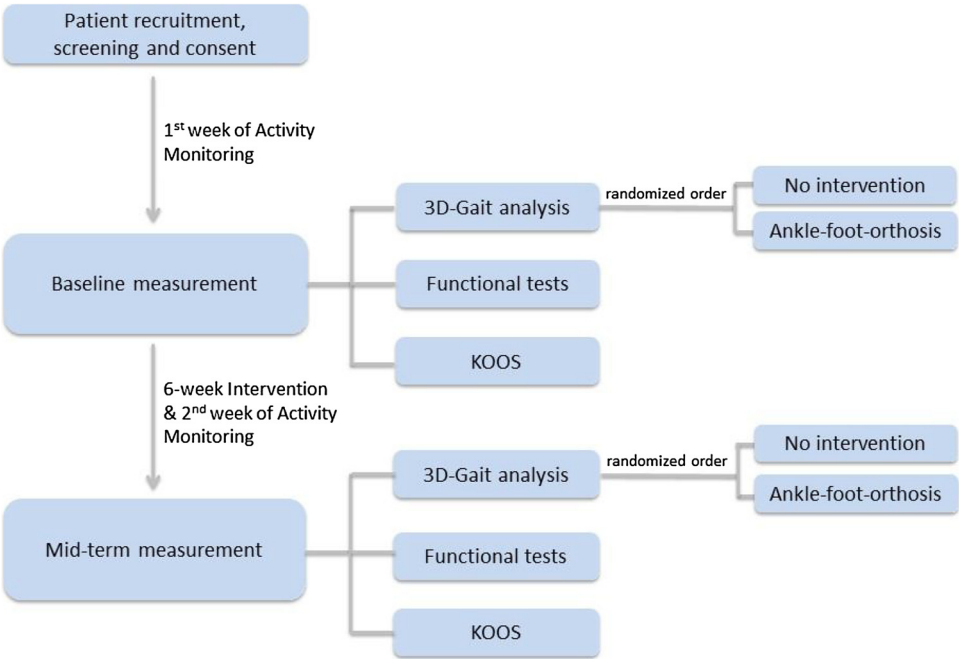

Fig. 1. Study design.