CURRENT CONCEPTS REVIEW

The Effect of Biomechanical Footwear on Pain from Knee Osteoarthritis

E. Carlos Rodriguez-Merchan, MD, PhD[1]; Hortensia De la Corte-Rodriguez, MD, PhD[2]; Juan M. Roman-Belmonte, MD, PhD[3]

Research performed at the the Department of Orthopedic Surgery, La Paz University Hospital-IdiPaz, Madrid, Spain

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Abstract

The effect of biomechanical footwear on pain from knee osteoarthritis (OA) is still unclear and controversial. The purpose of this article is to review the literature with the aim of answering the following question: What is the impact of biomechanical footwear on pain from knee OA? A Cochrane Library and PubMed (MEDLINE) search related to the effect of biomechanical footwear on pain from knee OA was performed. Several authors have reported knee pain alleviation in people with knee OA using biomechanical footwear. However, many of them have also stated that further investigation was required to evaluate its long-run effectiveness and safety, as well as replication, prior to reaching conclusions about the clinical value of this treatment. The cost of biomechanical footwear treatment is around 5,000 US dollars. Considering the weak evidence currently available on the efficacy of biomechanical footwear and its high cost, we do not advise the routine use of that treatment until it can be unequivocally confirmed that it is truly effective for pain alleviation in patients with knee OA.

Level of evidence: III

Keywords: Biomechanical footwear, Efficacy, Knee, Osteoarthritis, Pain

Introduction

Knee osteoarthritis (OA) afflicts millions of people all around the world (1). Moreover, the frequency of knee OA is increasing due to population aging and the high incidence of obesity. Acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), and opioids are most usually utilized to manage the pain associated with OA of the knee joint and are related to complications (2-6).

Biomechanical footwear for knee OA has been built up to diminish pain, ameliorate physical function, and conceivably decelerate sickness advancement, but evidence of their efficacy has been indecisive (7-9).

The purpose of this article is to carry out a narrative review of the literature with the aim of answering the following question: What is the effect of biomechanical footwear on pain from knee OA?

A Cochrane Library and PubMed (MEDLINE) search related to the impact of biomechanical footwear on pain from knee OA was carried out. The main criteria for selection were that the articles were focused in the effect of biomechanical footwear on pain from OA of the knee joint. Our search strategy (PubMed /Medline and Cochrane Library) is shown in [Figure 1]. The key words were "biomechanical footwear AND knee osteoarthritis". The searches were made since the existence of the search engines (PubMed and Cochrane Library) until 7 December 2020.

Biomechanical footwear

A biomechanical footwear called Apos System (AposTherapy - Sports and Medical Technologies Ltd., Herzliya, Israel) was described in 2010 by Bar-Ziv et al and was individually adapted to patients suffering from knee OA (10) [Figure 2]. According to the treatment plan and pricing reported by AposTherapy, the cost of treatment is around 5,000 US dollars (11). This price includes the following standard program components: one personalized footwear; 1 year of follow up monitoring;

Corresponding Author: E. Carlos Rodriguez-Merchan, Department of Orthopedic Surgery, La Paz University Hospital-IdiPaz, Madrid, Spain
Email: ecrmerchan@hotmail.com

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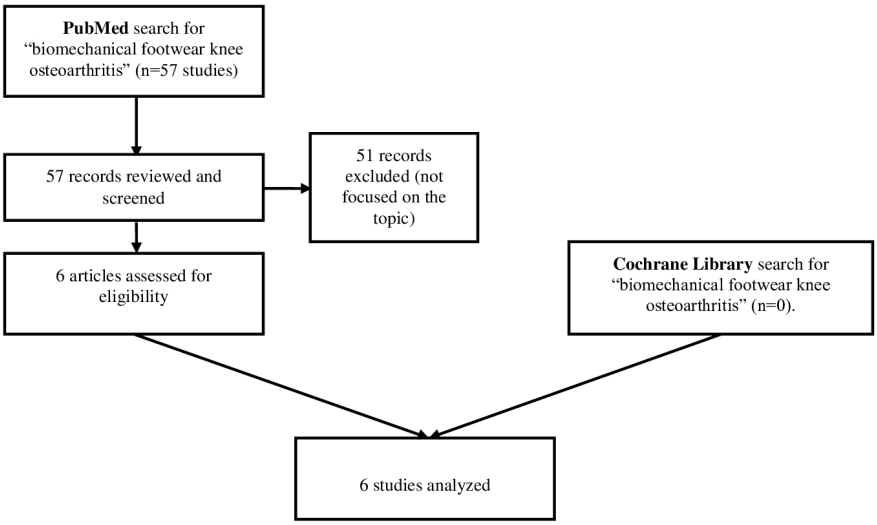

Figure 1. Flow chart of our search strategy regarding the effect of biomechanical footwear on pain from knee osteoarthritis (OA).

care from a qualified trained clinician; a personalized management program; five follow-up consultations; adjustments of elements of the device according to the clinical requirements at the follow-up consultations; and patient support services.

Improvement of pain

In 2010 Bar-Ziv et al reported a prospective controlled study on the impact of management with Apos System on the level of pain in patients with knee OA (10) [Figure 2]. Fifty-four patients with bilateral knee OA were enrolled to treatment (N=29) and control (N=25) groups. Patients were assessed before treatment, and at 4 weeks and 8 weeks. The biomechanical footwear used in this study was individually adapted to each patient in the treatment group. In the control group, an exactly identical foot platform was placed (so that the footwear could not be distinguished from the real footwear), but without the biomechanical structures of the real biomechanical footwear: two convex-shaped components connected to the patient's feet [Figure 2]. One was placed under the hindfoot area and the other was placed under the forefoot area. The components were connected to the patient's foot utilizing a platform in the form of a shoe. The platform had an especially designed sole that involved two mounting rails that allowed flexible placing of each component under each area. Treatment included two stages, the first brought the knee to lessened pain alignment and the second applied perturbations while walking. In the *varus* knees (OA of the medial compartment) the component under the hindfoot was displaced laterally from the baseline location. This displaced the center of pressure in the foot laterally, therefore diminishing the amount of the adduction moment acting on the knee joint. This was performed until the patient reported exiguous ache when initial contact. The component under the forefoot was displaced medially from the baseline location until the patient reported exiguous ache during mid-stance. When the desirable alignment was accomplished, the patient reported instantaneous ache alleviation while walking. Perturbation was accomplished by walking on two convex shaped components that produced controlled instability in gait. Primary parameters were the Western Ontario and McMaster Osteoarthritis Index (WOMAC Index) (12) and the Aggregated Locomotor Function (ALF) assessment (13). After an 8-week follow-up, significant differences were observed between the two study groups. While in the control group the WOMAC (pain and function) and ALF did not improve, in the treatment group the average improvement in pain on the WOMAC scale was approximately 65%. The ALF scale improved on average by 31%. Bar-Ziv et al concluded that the biomechanical footwear was efficacious in diminishing pain and in patients with

Figure 2. The Apos System iomechanical footwear (AposTherapy®) is shown (image taken from the Internet).

knee OA (10).

In 2012 Drexler et al assessed efficacy of Apos System on pain, function and quality of life of patients with medial compartment knee OA (14). Six hundred and fifty-four patients were evaluated prior to and following 12 weeks of Apos System treatment. The biomechanical footwear ameliorated knee pain of patients with medial compartment knee OA. That was why Drexler et al advised that the Apos System should be included in the treatment of knee OA (14).

In the Biomechanical Therapy for Osteoarthritis of the Knee (BIOTOK) randomized clinical trial reported in 2020 by Reichenbach et al analyzed the impact of Apos System on knee pain in patients with knee OA (treatment group) and compared it to a control group (15). They observed that the use of the Apos System improved the pain at 24 weeks of follow-up, compared to the control group. However, these authors stated that such improvement was of uncertain clinical importance and that their study had several notable limitations. That is why these authors stated that further investigation would be required to evaluate long-run effectiveness and safety, as well as replication, prior to reaching conclusions about the clinical value of the Apos System (15).

Improvement of pain, function and quality of life

In 2013 Bar-Ziv et al reported the long-run impacts of the Apos System in patients with

knee OA (two-year follow-up study) (16). A series of patients with painful knee OA was analyzed, divided into two groups comparable to each other before carrying out the treatment: the treatment group (biomechanical footwear) and the control group. WOMAC, ALF, Short Form-36 Health Survey (SF-36) and Knee Society Score (KSS) were evaluated. In the treatment group, an improvement of all scales was observed, which did not happen with the control group. At two-year follow-up, the treatment group exhibited significantly better results. The biomechanical footwear significantly diminished pain and ameliorated function and quality of life of patients with knee OA over the long run (16).

Improvement of pain and gait parameters

In 2014 Elbaz et al assessed the effect of the Apos System on the level of pain and gait patterns in a 58 patients suffering from bilateral medial compartment knee OA (17). All patients experienced a computerized gait test and were assessed by means of WOMAC and SF-36. The patients were assessed again 6 months after starting the treatment, and an improvement of all the gait parameters analyzed was observed. Knee pain was reduced by approximately 68% (17).

Improvement of pain, function and quality of life and gait patterns

In 2020 Miles and Greene reported a retrospective analysis to assess the impact of treatment with the Apos System on subjective and objective parameters in patients with knee OA (18). Treatment with the biomechanical device led to a significant amelioration in gait patterns, pain, function and quality of life for patients suffering with knee OA. However, these authors stated that further studies in controlled settings were needed to confirm its clinical impact further. It seemed to produce an equivalent response between patients that had already been advised total knee arthroplasty (TKA) and those that had not been advised, thereby conceivably providing an alternative solution for these people. If these outcomes could be maintained in the longer run, it could theoretically postpone or even elude the necessity for TKA in many cases. The results of this study suggested that Apos System can ameliorate gait patterns, pain, function and quality of life (18).

There are several limitations in Bar-Ziv et al studies (10,16): low number of patients, all patients had a *varus* knee alignment and the two groups were not randomized.

Drexler et al, and Elbaz et al studies were uncontrolled studies conducted by the manufacturers (14, 17).

The Miles and Greene study was a retrospective analysis of patients from the centers database and therefore had no control group (18).

Because of the limited number of randomized control trials (only one), it is not possible to make a definitive conclusion about the Apos System on knee joint pain caused by OA. Subsequently, a follow-up period of at least five years is needed because OA of the knee is a chronic disease.

No studies compared the Apos System with operative treatment such as high tibial osteotomy (HTO) or unicompartmental knee arthroplasty (UKA).

Although several authors have reported knee pain alleviation in people with knee OA using the Apos System, many of them have also stated that further investigation is required to evaluate long-run effectiveness and safety, as well as replication, prior to reaching conclusions about the clinical value of this treatment. Considering that and the high cost of the Apos System treatment, we do not advise its routine use until it can be unequivocally confirmed that it is truly effective in patients with OA of the knee joint.

E. Carlos Rodriguez-Merchan MD PhD[1]
Hortensia De la Corte-Rodriguez MD PhD[2]
Juan M. Roman-Belmonte MD PhD[3]
1 Department of Orthopedic Surgery, La Paz University Hospital-IdiPaz, Madrid, Spain
2 Department of Physical Medicine and Rehabilitation, La Paz University Hospital-IdiPaz, Madrid, Spain
3 Department of Physical Medicine and Rehabilitation, Cruz Roja San José and Santa Adela University Hospital, Madrid, Spain

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