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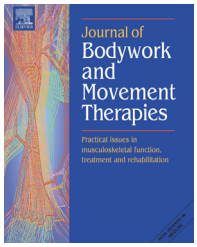

REVIEW: COMPLIANCE OF PATIENTS WEARING ORTHOTIC DEVICES

# Compliance of patients wearing an orthotic device or orthopedic shoes: A systematic review

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**Summary** *Background:* Alongside the positive effects of use of orthotic devices for the lower extremities (ODLE) and orthopedic shoes, complaints and criticism by users possibly lead to non-compliance.
*Objective:* The purpose is to determine the compliance of patients wearing an ODLE or orthopedic shoes and to describe the main reasons for using and not using.
*Methods:* Different online databases were searched for articles about patients' compliance with regard to an ODLE or orthopedic shoes. A methodological quality control was conducted.
*Results:* Ten studies (1576 patients) were included. The data revealed between 6 and 80% not users. Several reasons for not using the orthotic device were described (e.g. pain, discomfort and cosmetically unacceptable).
*Conclusions:* The high percentage of patients who are not wearing the prescribed orthotic devices leads to a high financial loss for society and a waste of therapeutic effort. These results should be taken into account during the design, construction and selection process of orthotic devices.


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## Introduction

Gait disturbance is a common problem in patients suffering from neurological pathologies (e.g. stroke, spinal cord injury, multiple sclerosis) (Balaban and Tok, 2014) or orthopedic problems (e.g. caused by diabetes mellitus or rheumatologic diseases) (Chan and Kong, 2013). An orthotic device for the lower extremities (ODLE) is frequently used to improve gait function. For example, an ankle-foot orthotic device (AFO) can be used in patients with foot drop (Ferreira et al., 2013). Improvements in step function by wearing an AFO have been reported in stroke patients, like beneficial effects on gait velocity, balance, ankle and knee kinematics and kinetics (Ferreira et al., 2013; Tyson and Kent, 2013). Also improvements in quality of life of the patients when using AFO's have been reported (Burns et al., 2006; Rome et al., 2004; Roos et al., 2006; Sheffler et al., 2013). In patients with rheumatoid arthritis orthopedic shoes are frequently prescribed to increase the comfort and support of the feet and the ankle (Kurup et al., 2012; Riskowski et al., 2011). These specialized footwear may change muscle activation and gait patterns to reduce joint loading during walking (Riskowski et al., 2011).

Besides the positive effects of an ODLE, it is reported that there are complaints and criticism of the users of these devices. As a consequence there is a decrease in the frequency of use, possibly leading to rejection of the devices. Patients' compliance is a common problem in rehabilitation, not only with regard to exercise and drugs therapy, but also regarding the use of devices (de Boer et al., 2009; Vinci and Gargiulo, 2008). For example, a patient's decision to use orthopedic shoes is influenced by various factors. These factors are not only related to gait function, but are a compromise between different aspects like cosmetic appearance, ease of use and an improvement in walking function (van Netten et al., 2012).

No systematic review articles about patients' compliance with respect to ODLE and orthopedic shoes were found. An overview of the patients' compliance can clarify this issue and highlight the importance of stimulating the search for factors associated with this problem. Within this systematic review the primary aim is to give an overview of the published rates of compliance in patients wearing an ODLE or orthopedic shoes. The primary research-question is: 'What is the compliance of patients wearing an ODLE or orthopedic shoes?'. Secondly the studies were analyzed with regard to possible reasons for using and not using the devices.

## Methods

### Search strategy

Four different databases were searched for relevant articles (last search in June 2014): PubMed, Web of Science, Pedro and Cochrane Library. The most important key-words were: "Orthotic devices", "Foot orthoses", "Lower extremities", "Orthopedic shoes", "Patient compliance", "adherence", "behavior" and "satisfaction". Whenever possible "MeSH-terms" (Orthotic devices, Self-help devices, Foot diseases/Utilization OR Therapy, Lower extremities, Gait, Walking, Questionnaires, Patient compliance, Behavior, Adherence, Satisfaction) were used. The same terms and combinations were used in other databases whenever possible. Afterward the reference lists from the included articles were searched for additional relevant studies.

### In- and exclusion criteria

Exclusion was based first on title, secondly on abstract and if an abstract was not available or did not provide enough information, the full text of the papers was read entirely. Pre-, quasi and true experimental studies were included if they were in English, French or Dutch and about adult patients with a prescribed ODLE or orthopedic shoes, where the compliance (e.g. users and not users, frequency of use) was reported.

### Quality control

After the selection of articles based on the in- and exclusion criteria, an examination of the methodological quality of each article was conducted using the methodological checklist "Critical review form quantitative studies" (Evidence-based rehabilitation, 2008). It was decided to delete the questions about outcome measures and intervention because this paper does not focus on intervention studies.

## Results

Key-word search in the different databases yielded 117 potential articles. After selection on title eleven articles remained and after reading the abstract and full text five articles were included in the review. Additionally, by searching reference lists and reading related articles five extra articles were included. In total, 10 studies were included (Burridge et al., 1997; de Boer et al., 2009; Fisher and McLellan, 1989; Jannink et al., 2005; Philipsen et al., 1999; Taylor et al., 1999; van Netten, Jannink, Hijmans, Geertzen and Postema, 2010b; Vinci and Gargiulo, 2008; Waaijman et al., 2013). Fig. 1 gives an overview of the search strategy.

### Quality control

In Table 1 the methodological quality scores are reported. All studies showed a cohort (5 studies) or cross-sectional (5 studies) design. In general the included papers stated the study purpose clearly and reported the background literature appropriately. Most of the studies (6 of the 10 studies) provided detailed information about the sample. Although, in none of the articles the sample size was justified. In our opinion the different studies used appropriate analysis methods, reported their results very well and gave clear conclusions. Taking into account the moderate to good quality of the studies and the limited number of relevant articles, we decided to include all ten studies.