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In-shoe plantar pressure measurements for the evaluation and adaptation of foot orthoses in patients with rheumatoid arthritis: A proof of concept study

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ABSTRACT

Objectives: Improving foot orthoses (FOs) in patients with rheumatoid arthritis (RA) by using in-shoe plantar pressure measurements seems promising. The objectives of this study were to evaluate (1) the outcome on plantar pressure distribution of FOs that were adapted using in-shoe plantar pressure measurements according to a protocol and (2) the protocol feasibility.
Methods: Forty-five RA patients with foot problems were included in this observational proof-of concept study. FOs were custom-made by a podiatrist according to usual care. Regions of Interest (ROIs) for plantar pressure reduction were selected. According to a protocol, usual care FOs were evaluated using in-shoe plantar pressure measurements and, if necessary, adapted. Plantar pressure–time integrals at the ROIs were compared between the following conditions: (1) no-FO *versus* usual care FO and (2) usual care FO *versus* adapted FO. Semi-structured interviews were held with patients and podiatrists to evaluate the feasibility of the protocol.
Results: Adapted FOs were developed in 70% of the patients. In these patients, usual care FOs showed a mean 9% reduction in pressure–time integral at forefoot ROIs compared to no-FOs ($p = 0.01$). FO adaptation led to an additional mean 3% reduction in pressure–time integral ($p = 0.05$). The protocol was considered feasible by patients. Podiatrists considered the protocol more useful to achieve individual rather than general treatment goals. A final protocol was proposed.
Conclusions: Using in-shoe plantar pressure measurements for adapting foot orthoses for patients with RA leads to a small additional plantar pressure reduction in the forefoot. Further research on the clinical relevance of this outcome is required.

1. Introduction

Inflammation, structural damage and deformities of foot joints are highly frequent in patients with rheumatoid arthritis (RA) [1–4]. These impairments may result in pain, alterations in the loading pattern of the foot during weight bearing [2,4–6] and subsequently to limitations in daily activities and a reduced quality of life [7,8].

RA related foot problems can be managed by providing custom made foot orthoses (FOs). Redistribution of plantar foot pressure, by creating a larger weight bearing area, is supposed to be one of the working mechanisms of FOs [9–11]. A recent systematic review showed FOs to be effective in reducing pain and high plantar forefoot pressures. However, only a moderate effect on pain reduction was found (pooled effect size 0.45) [12]. Improving the effects of FOs by using the immediate feedback from plantar pressure measurements seems promising [13,14]. To date, evaluation and subsequent adaptation of FOs is usually based on patient feedback.

A study of Bus et al. showed that adapting therapeutic footwear (including custom-made inserts) with the use of sequential

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in-shoe plantar pressure measurements resulted in footwear with better plantar pressure distribution properties in patients with diabetic neuropathy [14,15]. Because of the differences in foot pathologies between patients with diabetic neuropathy and patients with RA, we developed a specific FO adaptation protocol for patients with RA. With the protocol, we aimed to achieve a maximal reduction of plantar pressure in painful foot regions because of the established relationship between high plantar pressure and foot pain [6,9].

The objectives of the present study were to evaluate (1) the outcome on plantar pressure distribution of FOs that are adapted according to the developed protocol in patients with RA and (2) the feasibility of this protocol.

2. Methods

2.1. Protocol

For the present study, an existing protocol for adapting therapeutic footwear in patients with diabetic neuropathy [14] was modified, using relevant scientific literature in RA. Our research group, consisting of experts in the fields of podiatry, rehabilitation, rheumatology and biomechanics reached consensus on a draft protocol. Subsequently, this draft protocol was field-tested in seven patients. Adjustments were made based on the feedback of the patients and experts, leading to the protocol that was used in this study.

2.2. Process for designing usual care FO

According to usual care at our institute, the patient's medical history was assessed and physical examination was performed. Subsequently, custom made FOs were designed and manufactured by the podiatrist. These FOs were constructed using prefabricated, semi-rigid orthotic devices with a deep heel cup and contoured medial arch. The orthotic devices were heat-moulded to the patient's foot while using the functional suspension subtalar joint neutral position technique [16,17]. Based on the findings of the podiatrist, functional corrections [9–11,16] (i.e. varus-, valgus corrections, metatarsal bars and metatarsal domes) and shock absorbing padding could be added [10,16]. The FOs were covered with leather, EVA or cushioning material such as PPT.

2.3. Process for evaluation and adaptation of usual care FO

Regions of Interest (ROIs) were selected as regions of pain (as indicated by the patient) with relatively high plantar pressure (as measured in-shoe during walking). High plantar pressures in foot regions (hindfoot, medial midfoot, lateral midfoot, forefoot, hallux, toe 2–5) were determined by the podiatrist by viewing a plantar pressure distribution diagram of the feet of the patient. A tentative treatment goal for plantar pressure reduction by wearing FOs was a-priori defined. Based on previous studies [9,10] and our experiences during testing the draft protocol we aimed to achieve $\geq$20% plantar pressure reduction in each ROI. Plantar pressure was expressed as peak pressure–time integral (PTI: the integral of peak pressure over time measured in any sensor within the defined ROI). In order to evaluate the PTI change in ROIs, PTI with FOs was compared to PTI with shoes only (no FOs). If the treatment goal of $\geq$20% PTI reduction in selected ROIs was not achieved, FOs were adapted in order to further reduce PTI. Adaptations could consist of (change in) functional corrections and/or additional shock absorbing padding. Subsequent in-shoe plantar pressure measurements during walking, with adapted FOs, were taken. Again the PTI change in ROIs was evaluated, which could lead to new adaptations. A maximum of three rounds of in-shoe pressure measurements and FO adaptations was set, with a maximal time duration of 45 min.

2.4. Proof of concept study

2.4.1. Design

Patients of an outpatient center for rehabilitation and rheumatology (Reade, Amsterdam) in the Netherlands served as the study population for this observational proof-of-concept study. In-shoe plantar pressure measurements during walking were taken: (1) prior to the first appointment with the podiatrist (baseline), and (2) during the process of evaluation and adaption of FOs. In addition, descriptive measurements and measurements of pain and disability were taken prior to the appointment with the podiatrist. Follow up measurements were taken after 3 months (end of treatment). For the present study, data assessed at baseline were used.

To assess feasibility, semi-structured interviews with podiatrists and participants were held and characteristics of all individual FO processes were registered.

The medical ethics committee of the Slotervaart Hospital/Reade in Amsterdam approved this study and written informed consent was obtained from each patient.

2.4.2. Patients

Consecutive patients, who were referred by a rheumatologist for podiatric treatment in a specialized center for rheumatology and rehabilitation, were approached to participate in the present study. Inclusion criteria were: (1) RA diagnosed by a rheumatologist according to the revised criteria of the American Rheumatism Association [18], (2) referral for podiatric treatment because of RA related foot problems, (3) indication for FOs according to the podiatrist, (4) $\geq$18 years of age. Exclusion criteria were: (1) comorbid disease with potentially confounding foot involvement, (2) not able to walk independently without using aids, and (3) inability to fill out questionnaires because of language or cognitive difficulties.

2.4.3. Podiatrists

FOs were manufactured and adapted using the protocol by three podiatrists, accustomed to treating RA-related foot problems with 1.5, 5 and 11 years of experience.

2.5. Measurements

2.5.1. Descriptive measures

Sex, age, body mass index, disease duration and site(s) of foot symptoms as indicated by the patient were recorded. Disease activity was measured using the disease activity score including a 44 joint count (DAS-44) [19]. Joint damage of the feet on radiographs was scored by using the Sharp/van der Heijde method, including a score for foot joint erosion and a score for foot joint space narrowing [20]. The Platto-score was used to quantify forefoot deformity and rearfoot deformity [21]. The Foot Function Index (FFI) was used to measure foot pain and disability [22].

Radiographs of the feet were scored by a trained physician. All other measurements were performed by two independent clinical research assistants, trained in taking the measures in a standardized way.

2.5.2. Plantar pressure measurements

The Pedar-X system (Novel GmbH, Munich, Germany) was used to measure in-shoe plantar pressure while walking. Patients wore standard socks and shoes during all measurements in order to eliminate the effect of patients' own shoes and socks, allowing comparison between FO conditions. After accommodation to the