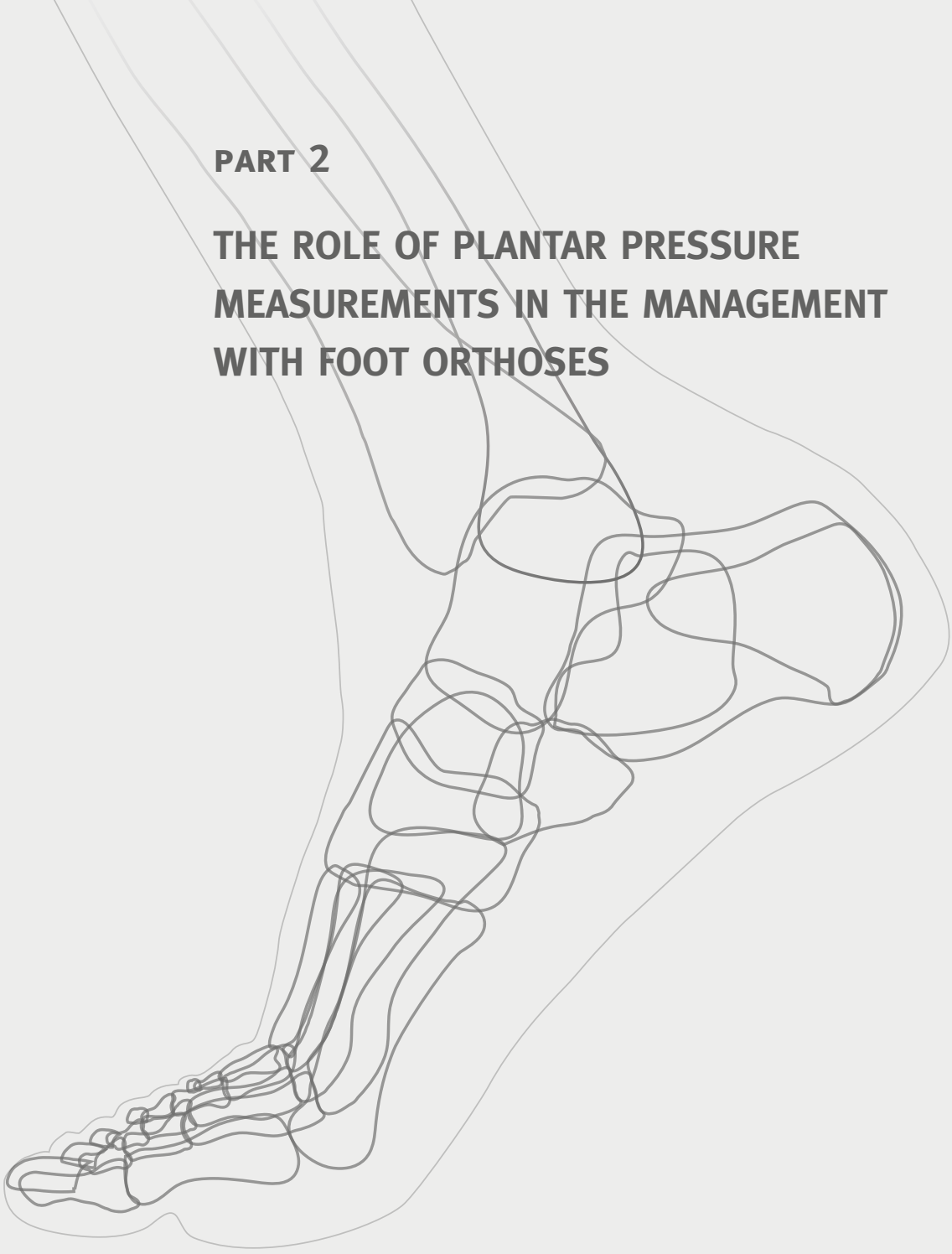
PART 2

THE ROLE OF PLANTAR PRESSURE MEASUREMENTS IN THE MANAGEMENT WITH FOOT ORTHOSES



CHAPTER 5

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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Gait & Posture. 2016;45:45-50

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.

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 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.

Methods

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.

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.

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 ≥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 ≥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 minutes.

Proof of concept study

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.

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) ≥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.

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.

Measurements

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.

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 system, a test trial was performed to determine comfortable walking speed. The actual measurement consisted of one trial of walking at a self-selected speed along a 25-meter walkway. During all measurements walking speed was monitored and when ≥15% deviant from the test trial, patients were asked to adjust their speed and the trial was repeated [23].

Using Pedar-X Step analysis software (Novel gmbh) 30 midgait steps were selected per measurement. Acceleration, deceleration and turning steps were excluded. Novel-projects software (Novel gmbh) was used to draw automatically a standardized mask that divided the foot into 6 regions, corresponding with the possible ROIs. PTI for each ROI was used to evaluate FO, since PTI is supposed to be an indicator for tissue stress and consequent foot pain [6, 24]. Additionally, peak pressure (PP) was recorded for each ROI.

Feasibility of the protocol

The feasibility of (1) the plantar pressure criteria used and (2) the process of adapting FOs was evaluated. Semi-structured interviews with all 3 podiatrists included the following topics: 'applicability and interpretability of measurements', 'clinical relevance of pressure criteria' and 'usefulness of adaptation process'. Semi-structured interviews with 10 participants (chosen as 1 out of 2 in the first sixteen, and the last two included patients) were held to gain feedback on patient's experience with the protocol, e.g. duration, fatigue, information obtained, and items to be improved. At the end of all interviews a faithful depiction of the experiences was achieved by verifying whether the remarks were interpreted in a correct way by giving a summary.

Characteristics of all individual FO processes were registered, including treatment goal, type of FO corrections, number of adaptation rounds, time duration, and reason for ending the process.

Analysis

In order to evaluate the outcome of the protocol on plantar pressure distribution, data of the in-shoe plantar pressure measurements were transferred to SPSS (SPSS, version 18, Chicago, IL). Pressure-time integrals and peak pressures at the ROIs of patients' feet were compared between the following FO conditions: 1) no FO *versus* usual care FO, and 2) usual care FO *versus* adapted FO. In addition, the plantar pressure distribution of the final FO that the patients took home (either usual care or adapted) was compared to no FO. Differences between FO conditions were calculated using paired t-tests and were considered significant at $P \leq 0.05$.

To evaluate the feasibility of the protocol and the a-priori defined plantar pressure treatment goal, the notes taken during the interviews with patients and podiatrists were summarized and registration forms were analyzed.

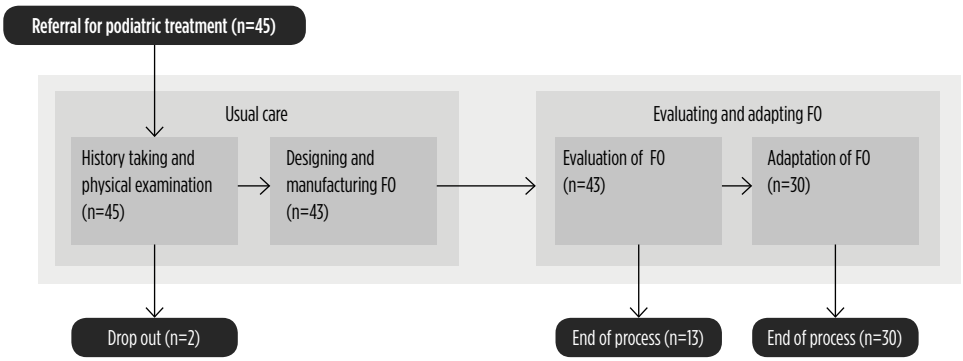

Figure 1. Flow of patients through the different phases of the process

Results

Descriptives

Forty-five patients were included in the present study. Two included patients dropped out due to non-response (n=1) and lack of space in standard shoes with FO (n=1). Data of 43 patients were analyzed: 33 women and 10 men, with a mean age of 53 years. Patient characteristics are shown in ***Table 1***. ***Figure 1*** shows the flow of patients through the various phases of the FO prescription and adaptation process.

Plantar pressure distribution

In total, 86 ROIs were selected in the feet of 43 patients. Nine selected ROIs were located in the rearfoot and five in the hallux. The majority of ROIs was located in the forefoot (84%). Therefore only forefoot ROIs were used in the analyses.

Usual care FOs were adapted in 30 of the 43 patients. In 25 of these 30 patients, forefoot ROIs were selected. In these patients, usual care FOs resulted in a 9% PTI reduction compared to no FOs in the 49 selected forefoot ROIs (mean reduction 8.87 kPa.s, 95% CI 2.36 to 15.38, p=0.01). FO adaptation led to an additional 3% PTI reduction (mean reduction 2.98 kPa.s, 95% CI 0.01 to 5.94, p=0.05) (see ***Table 2***). In 13 of the 43 patients, adaptation of usual care

Table I. Patient characteristics

Characteristics	Value
Age, years	53 (13.5)
Female, n (%)	33 (76.7)
Body-mass index, kg/m2	26.5 (6.4)
Disease duration*, years	5.5 (1.0;10.0)
DAS-44*	1.4 (0.9;2.3)
Sharp / van der Heijde score feet*	
foot joint erosion (range 0-120)	0.0 (0.0;1.0)
joint space narrowing (range 0-48)	0.0 (0.0;0.3)
Platto-score	
forefoot deformity* (range 0-12)	1.0 (0.0;3.0)
rearfoot deformity* (range 0-7)	1.0 (0.0;1.5)
Location of foot pain, n (%)	
rearfoot	3 (7.0)
forefoot	32 (74.4)
hallux	3 (7.0)
combination	5 (11.6)
Uni-/ bilateral foot pain, n (%)	
unilateral	7 (16.3)
bilateral	36 (83.7)
Foot Function Index	
pain (range 0-100)	43.2 (23.2)
disability (range 0-100)	33.4 (23.3)

Values are presented as mean ± SD unless otherwise indicated.
** Values are presented as median (IQR). DAS-44 = disease activity score.*

FOs was not performed for the following reasons: the treatment goal was reached (n=2), relatively low PTI in ROIs (n=8) and fatigue in patients (n=3).

Final FOs, either usual care or adapted, were prescribed in all 43 patients. In 37 of the 43 patients forefoot ROIs were selected. In these patients, final FOs resulted in a 10% PTI reduction compared to no FOs in the 72 selected forefoot ROIs (mean reduction 9.54 kPa.s, 95% CI 4.22 to 14.87, p=0.001) (see ***Table 3***). The a-priori defined treatment goal was reached in 29, out of 72, selected forefoot ROIs. No statistically significant peak pressure reduction in forefoot ROIs was found.

Feasibility of the protocol

The feasibility of the process of adapting FO appeared to be acceptable for a future study. All 10 interviewed patients were positive about the application of the protocol, i.e. the treatment was well tolerated and to satisfaction. All podiatrists gave positive feedback on the topics 'applicability and interpretability of measurements', and 'usefulness of adaptation process', and indicated that the use of in-shoe plantar pressure measurements offered guidance in the process of evaluation and adaptation of FOs.

Analysis of the individual FO processes showed that the duration of the process was feasible for the majority of patients (93%), except for three patients in whom the adaptation protocol was ended due to fatigue. Adaptation of usual care FOs was performed in 30 patients (70%): in 21 patients one adaptation round, and in nine patients two rounds were performed. A maximum of two adaptation rounds was feasible in 45 minutes. The defined plantar pressure

Table 2. PTI (kPa s) and PP (kPa) in forefoot ROIs with different FO conditions (n=25)

ROI	Number of ROIs	No FO (0)	Usual care FO (1)	Adapted FO (2)	Δ 0-1			Δ 1-2		
		Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	*95% CI*	*p-value*	*Mean (SD)*	*95% CI*	*p-value*
Forefoot	49									
PTI		97.21 (25.41)	88.34 (27.32)	85.36 (24.65)	-8.87 (22.66)	2.36 to 15.38	0.01	-2.98 (10.33)	0.01 to 5.94	0.05
PP		336.72 (82.12)	326.08 (99.61)	323.65 (101.32)	-10.64 (76.39)	-11.30 to 32.58	0.33	-2.42 (48.08)	-11.39 to 16.24	0.73

ROI=region of interest. FO=foot orthoses. PTI=pressure time integral. PP=peak pressure.

Table 3. PTI (kPa s) and PP (kPa) in forefoot ROIs without FO and with final FO (n=37)

ROI	Number of ROIs	No FO (0)	Final FO (F)	Δ 0-F		
		Mean (SD)	*Mean (SD)*	*Mean (SD)*	*95% CI*	*p-value*
Forefoot	72					
PTI		92.29 (24.71)	82.75 (23.63)	-9.54 (22.66)	4.22 to 14.87	0.001
PP		325.05 (83.43)	317.60 (96.65)	-7.45 (78.57)	-11.01 to 25.91	0.42

ROI=region of interest. FO=foot orthoses. PTI=pressure time integral. PP=peak pressure.

criteria were not acceptable for use in a future study. PTI reduction ≥ 20% in all determined ROIs was not feasible in the majority of patients: in only eight out of 43 patients this goal was achieved. According to the podiatrists, ≥20% plantar pressure reduction was not reasonable to achieve in each ROI.

Final protocol

The protocol was revised based on the evaluation of its feasibility. According to the final protocol, in-shoe plantar pressure measurements are performed prior to designing and manufacturing FOs. ROIs are selected based on site(s) of foot symptoms as indicated by the patient as well as on information from the pressure distribution diagram and the physical examination performed by the podiatrist. Based on the clinical reasoning process of the podiatrist, individual treatment goals are set in order to change the pressure distribution at ROIs. FOs are designed and custom-made by the podiatrist. Subsequently, FOs are evaluated with in-shoe plantar pressure measurements. When individual treatment goals are achieved the process ends. Otherwise, the FOs are adapted. ***Figure 2*** shows a flow chart of the final protocol.

Discussion

In the present study in-shoe plantar pressure measurements were used to evaluate FOs in patients with RA. Based on the feedback of these measurements adapted FOs were developed in 30 out of 45 patients (70%). In these patients, usual care FOs resulted in a mean 9% PTI reduction in forefoot ROIs compared to no FO. Adaptation of usual care FOs led to an additional mean 3% PTI reduction.

The study of Bus et al. [14, 25] in patients with diabetic neuropathy is to our knowledge the only study investigating a comparable protocol. In that study, adaptation of therapeutic footwear resulted in an additional mean PTI reduction of 24% in all ROIs [14]. The greater pressure reduction found by Bus et al. could be related to the intervention. Therapeutic footwear has a greater potential for plantar pressure reduction than FOs. The observed difference could also be related to the study population. Foot pathology and treatment strategy are different in RA patients with painful (sensate) feet compared to patients with diabetic neuropathy and insensate feet. The time needed to adapt to the FO in patients with sensate feet might be longer than in patients with insensate feet, which may have led to a suboptimal short-term effect on pressure distribution (i.e. smaller plantar pressure changes). To limit that effect a considerable amount of time was reserved for patients to walk with their FO before plantar pressure measurements were performed.

Improvement of the protocol related to the treatment goal was deemed necessary. One general treatment goal (≥ 20% PTI reduction in each ROI) in all participating patients was unrealistic. Instead, a mean PTI reduction of 10% was realized after FO intervention in our study. During the development of the protocol we presumed to include patients with mainly forefoot deformities

and subsequent high plantar forefoot pressures related to forefoot pain. However, patients with relatively short disease duration and few deformities were included, resulting in lower forefoot plantar pressures than found in studies that included patients in a more advanced disease stage [9, 10]. This might be the result of advances in early referral and tight disease control in RA

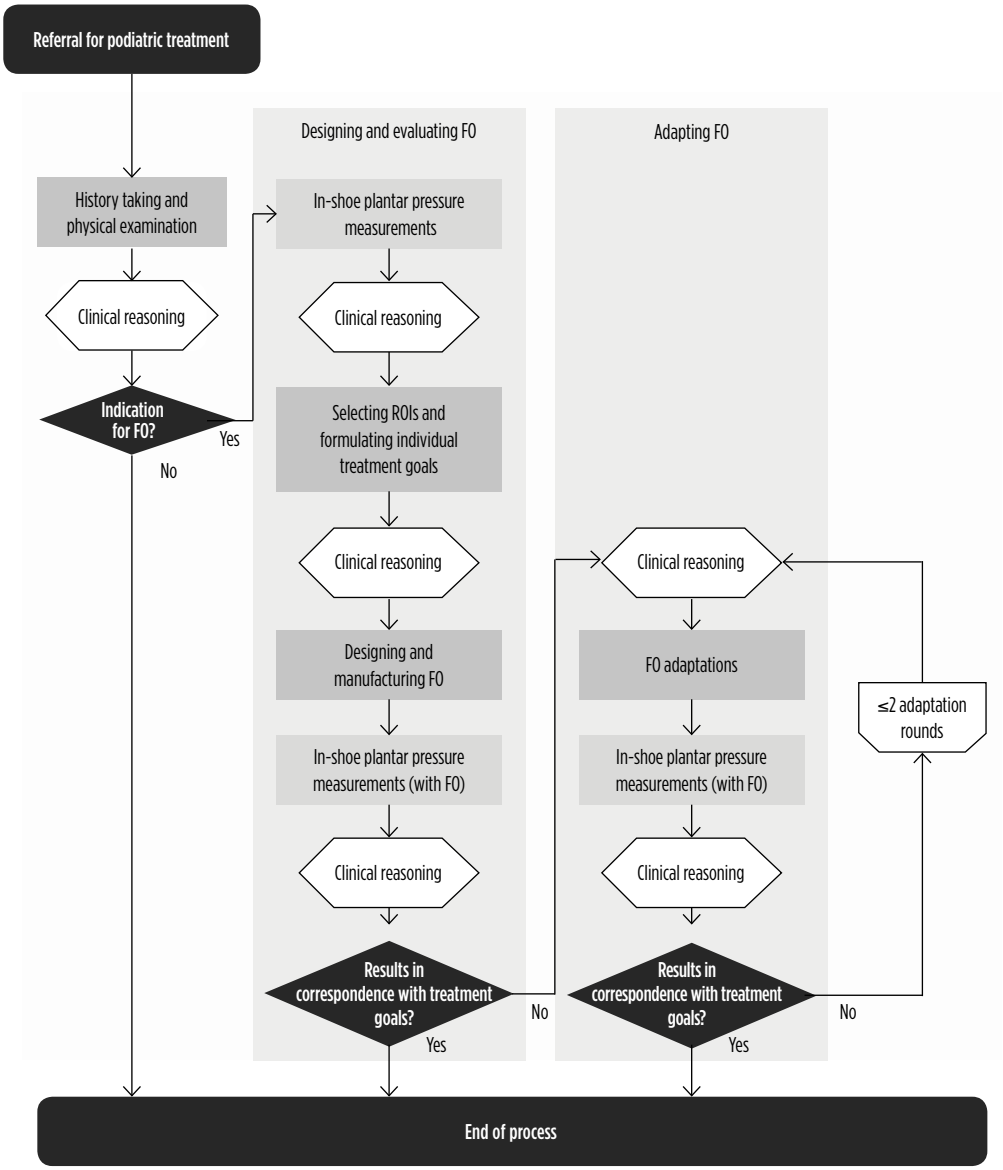

Figure 2. Flow chart final protocol

in recent years. Moreover, a forefoot offloading strategy was detected in some patients [26, 27]. In these patients, using FOs could normalize forefoot loading, resulting in increased forefoot PTI after FO intervention while in other patients decreased forefoot PTI after FO intervention was achieved. These different strategies are reflected by the large standard deviation around the mean PTI change found in our study (see ***Table 3***). In the final protocol individual treatment goals were proposed, instead of a general treatment goal.

The process for adapting FO was considered acceptable for a future study. Although fatigue was reported in only 7% of the patients it is an important aspect to monitor and adapt the process to, in clinical practice but also in future research.

Whether this protocol for adapting FOs with the feedback of plantar pressure measurements is (cost) effective in RA needs further investigation. The 3% additional PTI reduction found in the present study is based on a short term evaluation of biomechanical mode-of-action. Long term clinical impact of this PTI reduction will be reported in a separate manuscript, using data on pain and physical functioning assessed within the present study. Ultimately, a definitive RCT including health economic benefit is warranted. To set up a RCT stratification is recommended in order to control for confounding of pain and function driven by mechanical and/or inflammatory disease.

A limitation of the present study could be the selected study population. The majority of the study population was treated for early RA, with minimal foot joint damage and mild foot deformities, refraining us from conclusions regarding patients with a more advanced disease stage. Furthermore, patients were treated in an outpatient center for rehabilitation and rheumatology which may hamper the generalizability of the results to other care settings.

The results of the present study may have several implications for both clinical practice and podiatry education. First, in-shoe plantar pressure measurements can be used as an additional diagnostic tool in RA patients with foot problems; it provides insight in the relation between foot pain and plantar pressure during walking with shoes. Second, the immediate feedback of in-shoe plantar pressure measurements may offer guidance to the process of evaluation and adaptation of FOs.

In conclusion, using in-shoe plantar pressure measurements for adapting FOs, leads to a small additional plantar pressure reduction in the forefoot in patients with RA and foot problems. Further research on the clinical relevance of this outcome is required.

Acknowledgements

We would like to thank (1) the patients for participating in this study, (2) the patient research partners, Ms L. Maat and Ms. W. Hoogland, for their time, effort and recommendations, (3) the clinical research assistants for performing the measurements and (4) the podiatrists for performing the protocol. In addition, we would like to thank Durea and Bimakon for making shoes available for this project. We thank the Dutch Arthritis Association for financially supporting this project.

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