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The effect of foot orthoses on gait biomechanics and pain among people with rheumatoid arthritis: A quasi-experimental study

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ABSTRACT

Background: Foot pain is frequent among people with rheumatoid arthritis (RA). Foot orthoses (FO) are commonly prescribed with the intention to reduce pain symptoms and improve function.
Research question: How do a custom-made FO affect pain, gait biomechanics and daily activity among people with RA?
Methods: Twenty-five participants with RA and foot pain completed this quasi-experimental study using a control insole for four weeks and then a custom-made FO in the following four weeks. The foot orthoses were customized by plantar foot shape targeting optimal restoration of normal arch height. A visual analog scale was used to monitor changes in ankle/foot, knee, hip joints, and global arthritis pain. In addition, the perceived pain area was measured using a body chart analysis. Kinematics and kinetics of the hip, knee and ankle joints during gait were analyzed using 3D-motion capture. Daily steps were measured with a wrist-based activity tracker for both the control insole and custom-made FO period, respectively.
Results: In comparison to the control insole, the custom-made FO reduced ankle/foot pain intensity ($p < 0.001$) in addition to a reduction of the perceived pain areas in the feet ($p < 0.001$), legs ($p = 0.012$), as well as the arms and hands ($p = 0.014$). Ankle plantar flexion and eversion moments were also reduced ($p < 0.001$). No difference in daily steps was observed between the two periods ($p = 0.657$).
Significance: This study has demonstrated an ankle/foot pain-relieving effect in conjunction with alterations of the ankle joint moments in people with RA using custom-made FO. The pain relief is plausibly attributed to alterations of the ankle joint moments when using the custom-made FO. However, future studies are needed to explore further into therapeutic implication of custom-made FO in pain management of people with RA.

1. Introduction

Rheumatoid arthritis (RA) often leads to impairments of the foot and ankle with associated disabilities [1]. Foot orthoses (FO) are the first line of conservative treatment for people with RA and foot pain targeting joint and soft-tissue pain, deformity, and joint instability [2,3]. FO is a therapeutic in-shoe medical device used to support, prevent, align and treat lower extremity, foot deformities and malalignment [4]. However, the clinical effectiveness of FO remains controversial. [5]. Nevertheless, there is evidence that FO can reduce pain, plantar pressure, and ankle joint eversion [2,3,6–9]. Previous work examining the biomechanical effect of FO among other patient groups has reported altered joint kinematics and kinetics of both the knee and hip joints [10]. A recent review has encouraged investigating lower limb kinematics, kinetics,

Abbreviations: RA, Rheumatoid arthritis; FO, Foot orthoses; SPM, Statistical parametric mapping; VAS, Visual analog scale; DAS28, 28 Joint Disease Activity Score; HAQ, Health Assessment Questionnaire.

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and pain in response to FO [11]. We have previously documented that a custom-made FO (customized with respect to the medial longitudinal arch height and contour) compared to a control insole (flat insole) reduced the pressure under the metatarsophalangeal joints, ankle plantar flexion moment and ankle eversion moment among people with RA [12]. However, it remains unclear if these changes also lead to pain relief. In the early stages of RA,synovitis in the metatarsophalangeal joints is a common cause of foot pain [13]. As the disease progresses, mid-, rearfoot and the ankle joints may become involved. Additionally, the combined plantar flexors, everters, and inverter muscles of the foot in people with RA are at high risk of developing chronic tendon inflammation and then becoming dysfunctional, which may lead to development of pes planus [14]. Therefore, a custom-made FO, reducing the ankle plantar flexion moment, ankle inversion, and eversion moments in conjunction with reduced pressure under the metatarsophalangeal joints could be a beneficial strategy to unload the joints and muscles to reduce foot pain.

We hypothesized that four weeks' usage of a custom-made FO from Simonsen et al. [1] compared to the control insole would: (I) reduce pain intensity and (II) maintain the reduced ankle plantar flexion moment and ankle eversion moment. This study aimed to assess whether FO-induced altered kinematic and kinetics leads to pain relief among people with RA [12]. In addition, adherence and daily activity was also monitored as secondary outcomes.

2. Methods

2.1. Participants

Participants were recruited between October 2018 and November 2019 from three different rheumatology departments in Denmark (North Denmark Regional Hospital, Aalborg University Hospital, and the Danish Rheumatism Hospital, respectively).

Study inclusion criteria were as follows: adults (>18 years) with a diagnosis of RA (ACR/EULAR criteria [15]), self-reported foot pain with a medically assessed need for custom-made FO, Participants were excluded if they have had changes in their disease-modifying anti-rheumatic medication and nonsteroidal anti-inflammatory and steroid treatment within the last four weeks to avoid potentially large changes in disease activity due to changes in medication. Participants were excluded if they had documented radiographic evidence of bone deformities or joint erosions in the foot and/or ankle, were currently or previously using custom-made FO within the last three months, had a diagnosis of inflammatory or degenerative joint disease of the spine, knee, and hip joints, had severe ischemic or neurological sequelae in the lower extremities, or a body mass index more than 32. Health Assessment Questionnaire (HAQ) score and 28 Joint Disease Activity Score (DAS28) were obtained from the patient's journal in conjunction with the most recent outpatient consultation.

2.2. Protocol

This quasi-experimental study took place at the motion analysis laboratory at Aalborg University. Over eight weeks, participants underwent a four-week initial test period using a control insole, a flat latex insole (Matas, Lillerød, Denmark) used daily (Fig. 1). In the following four-week period, a custom-made FO was used.

Each custom-made FO was customized to the plantar geometry of the medial longitudinal arch height and contour of each participant. The foot shape was captured using a foam impression box with the foot held in a neutral corrected pose in a full weight bearing setting [12]. The degree of motion control of the rear- and forefoot was controlled during the imprint by stabilizing the ankle complex with a hand [12]. Ethylene-vinyl acetate was used as the orthotic shell material. The shell was three-quarters length extending to the toe sulcus without cushioning.

The participants were instructed to use the FOs as much as possible. They were recommended to take a break for the rest of that day if they felt discomfort. The participants used the insoles in their own shoes between the sessions. The participants performed the gait trials in a standardized neutral shoe, Energy Cloud 2 (Adidas AG, Herzogenaurach, Germany).

The study consisted of three sessions: (1) a baseline session at the North Denmark Regional Hospital, where baseline measures were obtained (VAS scores, questionaries and body charts) and foot imprints were taken (session 1 took 45 min); (2) a gait analysis session walking with the control insole after usage for four weeks, and (3) a final gait analysis session, where the participants walked with the custom-made FO after intervention for four weeks (session 2 and 3 took 1,5–2 h each);. VAS scores, questionaries and body charts were also collected at session 2 and 3.

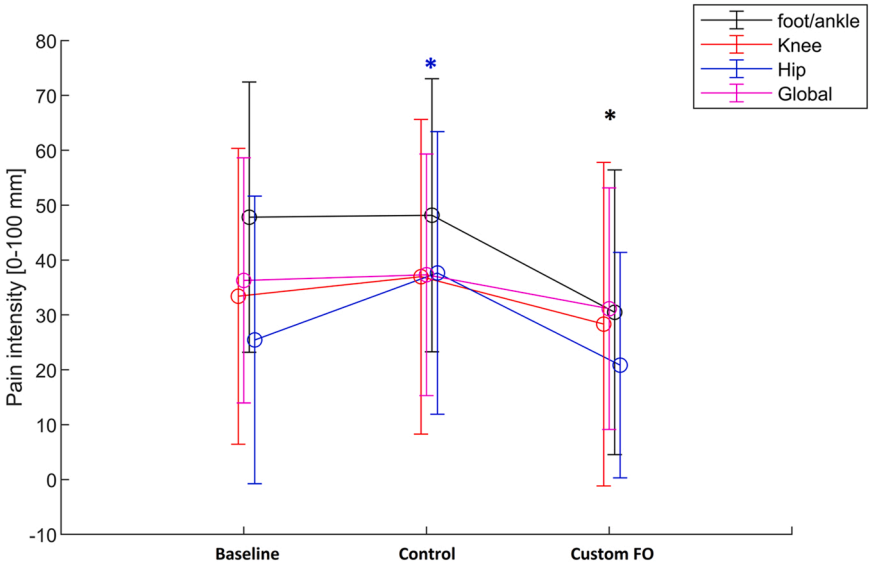

Fig. 1. Pain intensity (VAS) values for the foot/ankle, knee, hip, and global. Statistical difference is marked with colored star corresponding to the parameter that is statistically different.

2.3. Pain intensity and location

Pain intensity was assessed on a 0–100 mm visual analog scale (VAS; 0 = no pain, 100 = worst imaginable pain) for global arthritis-related pain, foot/ankle region, knee joint, and hip joint, respectively, in each of the three sessions. Moreover, pain drawings were used to document the location of the pain [16,17]. The participants were instructed to shade the areas they experienced pain with an ink pen on an anatomical body chart. The anatomical body charts were scanned in a.jpg format. For the analysis, the shaded area was measured using Adobe Acrobat Pro DC v.2019.021.20058 (Adobe, San Jose, California, USA). A grid overlay was used to divide the anatomical drawings into four zones: feet, lower limb, arms+hands, and trunk+neck+head. Graphical visualization of the average anatomical body chart for all participants was made in MATLAB v. R2019b (The MathWorks, Inc., Natick, Massachusetts, USA).

2.4. Gait analysis

An infrared eight-camera system measured the participant's gait at 100 Hz (Oqus 300 series, Qualisys, Sweden). Ground reaction forces were measured with force plates (AMTI, USA) recording with 1000 Hz. A modified version of the plug-in gait marker protocol was used. Compared to the plug-in gait model, additional markers were placed on the medial femoral epicondyles, medial malleoli, and the head of the 1st and 5th metatarsals [18]. Six overground gait trials were performed before and after the custom-made FO intervention period at a self-selected speed.

2.5. Inverse dynamics

An inverse dynamic model was created for each patient using the AnyBody Modelling System version 7.2.3 (AnyBody Technology A/S, Aalborg, Denmark) to estimate joint angles and joint moments of the right leg. Specifically, the Anatomical Landmark Scaled Musculoskeletal Model was used [19]. Joint angles and joint moments were represented in joint coordinate systems defined following the International Society of Biomechanics' recommendations [20].

Walking speed was calculated by averaging the four pelvis markers' horizontal velocity [21]. The stance phase duration was normalized to 100% of stance. Joint moments were normalized to the percentage of body weight and body height.

2.6. Wearing time

Adherence was measured using OrthoTimer (Rollerwerk, Müncehn, Germany), a temperature sensor that was inserted into the custom-made FO during the entire intervention period. The sensor stores time, date, and temperature every 15 min. As the control insole was thinner than the sensor, adherence measurements for the control insole were impossible.

2.7. Daily steps

The participants wore a wrist-based activity tracker Polar M200 [22] (Polar, Kempele, Finland) during the eight-week study period. The participants were instructed to wear it as much as possible during waking hours. Daily steps were extracted and averaged for both four-week periods.

2.8. Ethical considerations

The participants were given written and verbal study information, and written informed consent was obtained. This study was conducted following the Declaration of Helsinki. The local committee on health research ethics granted ethical approval for this study (N20180007).

2.9. Statistics

Power analysis was performed in G*Power version 3.1.4. Effect size (0.61) was calculated from the peak plantar flexion moment from a pilot study using confidence level ($\alpha = 0.05$) and desired power (80%) with a Wilcoxon signed-rank test. The required sample size was 25 participants but, to accommodate potential dropouts, twenty-seven participants were included in the study.

Non-parametric, Wilcoxon signed-rank test was used to compare pain intensity, area of pain, and daily steps. The pain area of the body charts was compared using the Friedman test. Spearman correlation analysis was performed between pain intensity and adherence to the custom-made FO. Statistical analyses were performed in SPSS v26 (SPSS Inc., Chicago, IL, USA) with an Alpha level set to 0.05.

The statistical parametric mapping version of the paired t-test was used to assess differences for the entire time series in joint moments and joint angles after the control period and after the custom-made FO intervention period [23]. All SPM analyses were performed using the open-source spm1d code [23] (v.0.4, spm1d.org) in MATLAB (R2020B) (The MathWorks, Inc., Natick, Massachusetts, USA).

3. Results

3.1. Patient demographics

Twenty-seven participants were included in the present study, but two dropped out before the final measurements, and, therefore, all their data has been excluded from the analysis. The average (± SD) demographic and clinical characteristics of the 25 participants (17 females) are presented in Table 1. The participant's median usage of the custom-made FO was 4.55 h per day (IQR: 2.7–7).

3.2. Pain intensity

Average pain intensity scores are presented in Fig. 2 for global arthritis, foot/ankle, knee, and hip. Foot/ankle pain intensity was reduced at closure of the custom-made FO intervention (median = 21 mm, IQR: 9.2–55.7 mm) compared to closure of the control intervention (median = 45.5 mm, IQR: 25–68.7 mm), ($Z(24) = -3.365$, $p < 0.001$) and baseline (median = 46 mm, IQR: 28.2–71.5 mm), ($Z(24) = -3.3836$, $p < 0.001$), but no differences were observed between the baseline and control intervention ($P = 0.786$). Hip pain intensity was increased at the end of the control (median = 35 mm, IQR: 12.60 mm) compared to the baseline (median = 17 mm, IQR: 0.75–45 mm), ($Z(24) = -2.9$, $p = 0.01$) but returned to the baseline value after the custom-made FO intervention (median = 16 mm, IQR: 2–43.2 mm), ($Z(24) = 2.9$, $p = 0.01$). Reduced foot/ankle pain intensity and adherence was not correlated (Spearman's $r = -0.243$, $p = 0.245$).

3.3. Pain location and area

Average layered body pain charts at the closure of the control and the custom-made FO interventions are presented in Fig. 3. The pain area of the ankle/foot was reduced at the closure of the custom-made FO

Table 1
Demographic and clinical characteristics of the 25 study participants with rheumatoid arthritis.

	Mean	SD
Age (years)	56.2	10
Body mass (kg)	84	16
Height (cm)	172.6	8.4
Disease duration (years)	3.6	1.9
Health Assessment Questionnaire score[1]	0.59	0.5
28 Joint Disease Activity Score[2]	2.47	0.7
Foot/ankle pain at baseline (VAS)	47.8	24.6

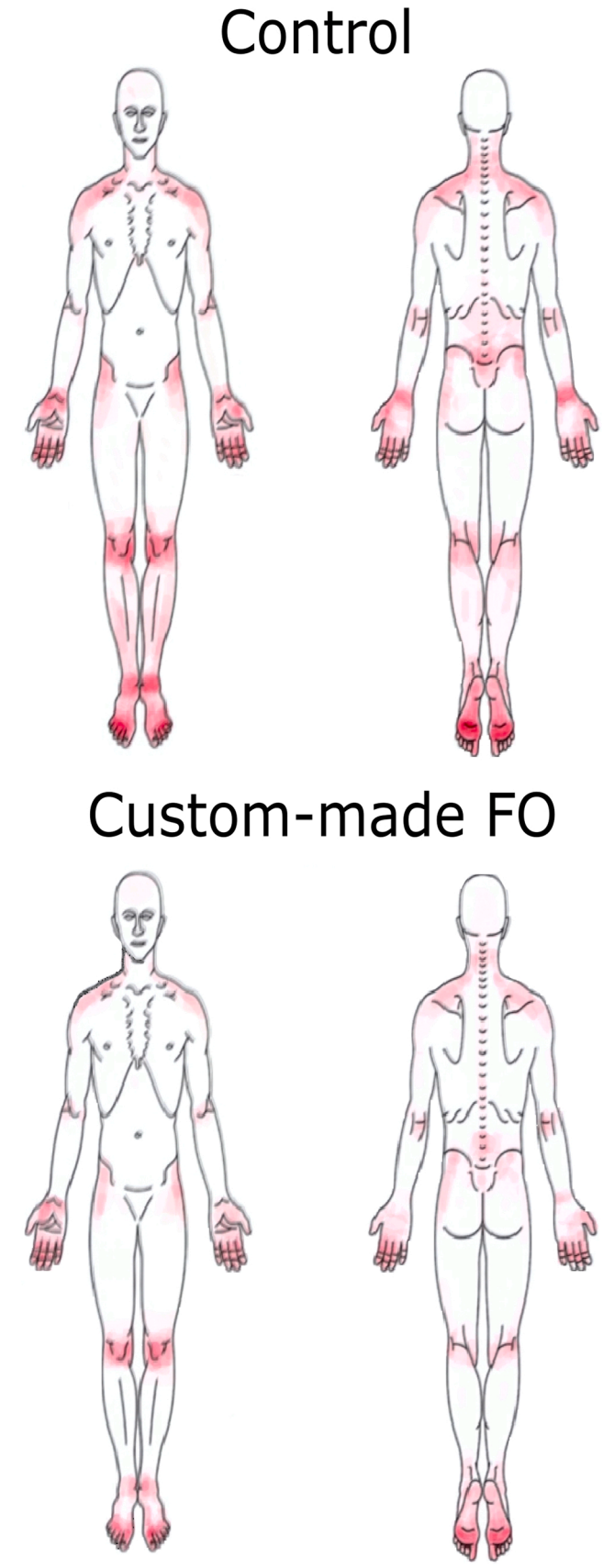

Fig. 2. Layered body chart at closure of the control and custom-made FO intervention.

intervention (median = 26.9 IQR: 11.7–56.6) compared to the control insole intervention period (52.69 IQR: 29.6–92.1, Z = −2.946 ($p < 0.01$)) (Fig. 4).

The perceived pain area of the legs was reduced at the closure of the custom-made FO intervention (median = 29.3, IQR: 0–51.1) compared to the closure of the control period (68.91, IQR: 10.1–153.5, Z = −2.9 ($p = 0.01$)). The perceived pain area of the hands and arms was reduced at closure of the custom-made FO intervention (median = 28.3 IQR: 0–71.7) compared the closure of the control period (median = 43.0, IQR: 10.8–125.5, Z = −2.902, P = 0.012) (Fig. 4).

3.4. Gait analysis

Walking speed was similar in the control insole (1.04 ± 0.16 m/s) versus the custom-made FO intervention (1.06 ± 0.17 m/s), t(24) = −0.496 ($p = 0.63$). Additionally, no difference was found for the duration of the stance phase between the two interventions: (control insole (0.76 ± 0.13 s) versus, custom-made FO (0.73 ± 0.07 s) (t(24) = 1.36 (= 0.19)).

No differences were found between the control and the custom-made FO for joint angles for the ankle, knee, and hip (Fig. 5). The ankle plantar flexion moment was reduced between 57% and 78% of the stance phase (average: 0.42% BW*BH) at the closure of the custom-made FO intervention compared to the closure of the control period (Figure 6) ((t(24)= 3.18 ($p < 0.001$)). The ankle eversion moment was reduced between 2% and 47% of the stance phase (average: 0.18% BW*BH) for the custom-made FO compared to the control insole (Figure 6) (t(24) = 3.20 ($p < 0.001$)). The knee adduction moment was increased between 19% and 76% of the stance phase (0.14% BW*BH) for the custom-made FO compared to the control insole (Figure 6), (t(24) = 3.27 ($p < 0.001$).

3.5. Activity

No statistical difference between the number of daily steps walked during the control period (median 9747 steps, IQR: 7536–14579.5 steps) and the custom-made FO period (median = 9853 steps, IQR: 6851–13659 steps) was observed (Z(24) = 0.444 ($p = 0.657$). The participants wore the step counter watch on average 80.8% (± 16.6%) of the day.

4. Discussion

The present study found reduced foot/ankle pain intensity in conjunction with reduced ankle plantar flexion and eversion moments after four weeks of using a custom-made FO compared to a preceding control period.

4.1. Pain intensity and body charts

The medium foot/ankle pain intensity reduction observed in the present study is consistent with previous studies, irrespective of FO customization used [24,25].

Body charts was used to evaluate changes in areas of perceived pain after the custom-made FO intervention in the present study [16,26]. The areas of perceived pain in the feet and ankles, in addition to the legs, were reduced at the closure of the period with custom-made FO compared to the control period. The characteristics of the custom-made FO, such as the contact support of the medial foot arch, might induce changes in the foot position during gait [8], leading to significant changes in gait patterns and further pain relief due to the cumulative off-loading effect [27].

In conjunction with the closure of the custom-made FO intervention period, we also found a reduced area of perceived pain in the arms/hands region. This reduction is an interesting observation that could indicate changes in central pain sensitization as result the intervention [28,29]. However, we cannot identify an exact explanatory mechanism

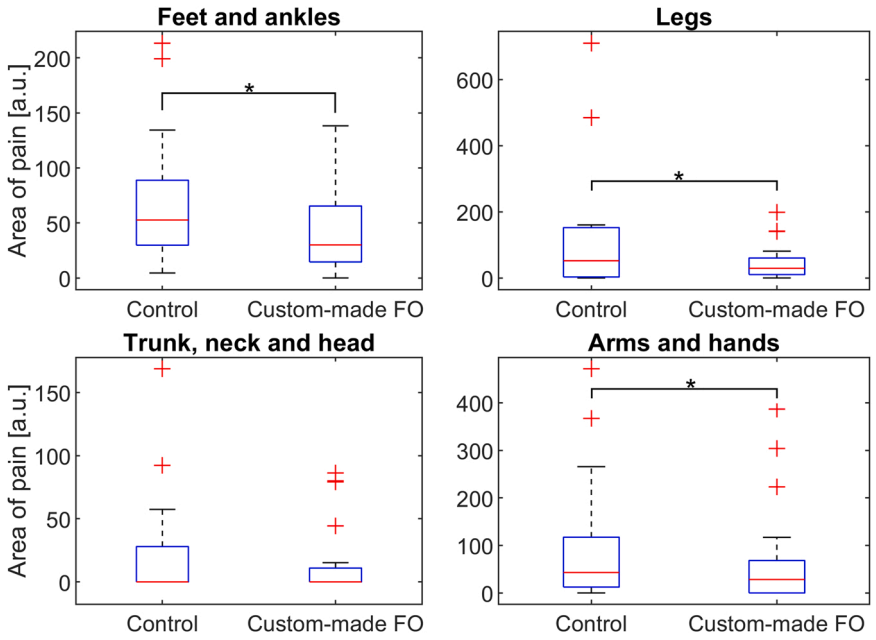

Fig. 3. Box plot of the area of perceived pain measured in the ankles/feet, legs, trunk/neck/head and hands/arms. Statistical difference is marked with a star.

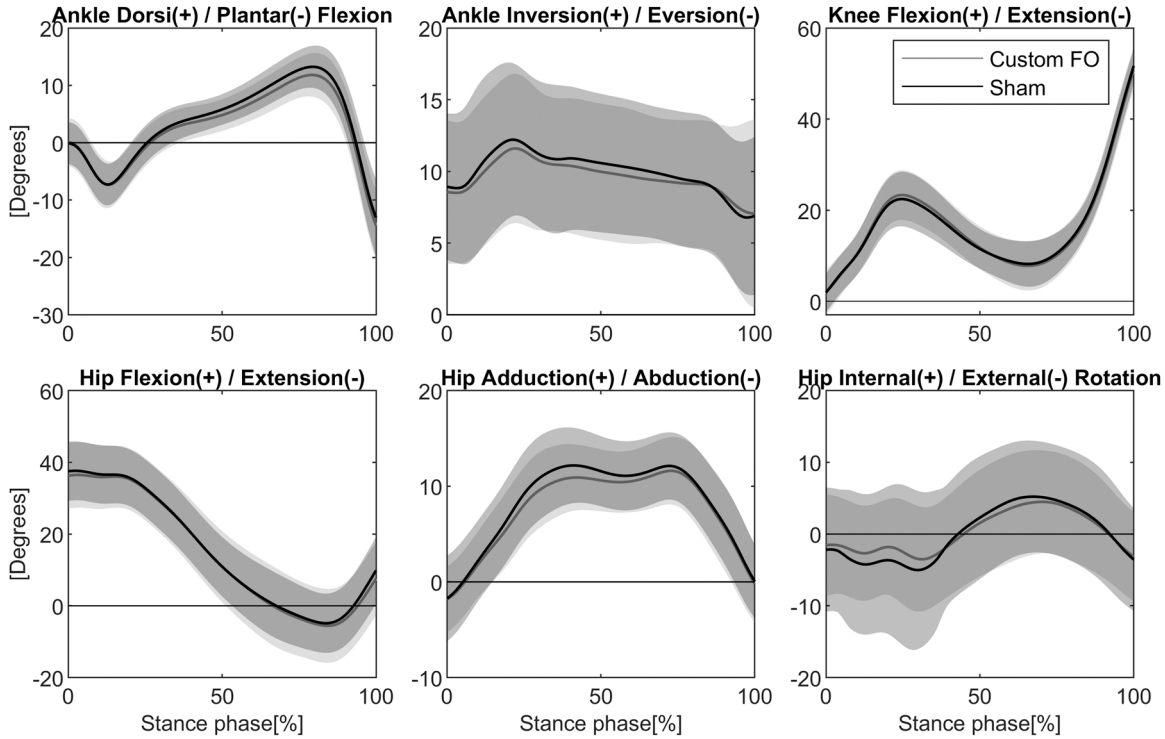

Fig. 4. Mean angles of the ankle, knee and hip joints, respectively. The black line is at closure of control insole, and the gray line is at closure of the custom-made FO intervention.

based on the study's methods. Therefore, these observations should be treated with caution. Further, specifically designed studies are needed to quantify to what extent custom-made FO can influence central pain sensitization.

4.2. Gait adaptations

Reduction in ankle plantar flexion and eversion moments were observed at closure of the four weeks custom-made FO intervention period. However, no difference in the ankle plantar flexion angle between the two periods was observed. Reduction of the ankle plantar flexion and ankle eversion moments is expected to result in an unloading of the plantar flexor and evertor muscles located in the lower leg [12]. The immediate effect of the custom-made FO on unloading the foot plantar flexor and inverter moments might explain the lower extremities' reduced painful area. Reducing the ankle plantar flexion and eversion moments might be a favorable approach since the muscles acting in these movements, frequently develop tendinopathy, especially

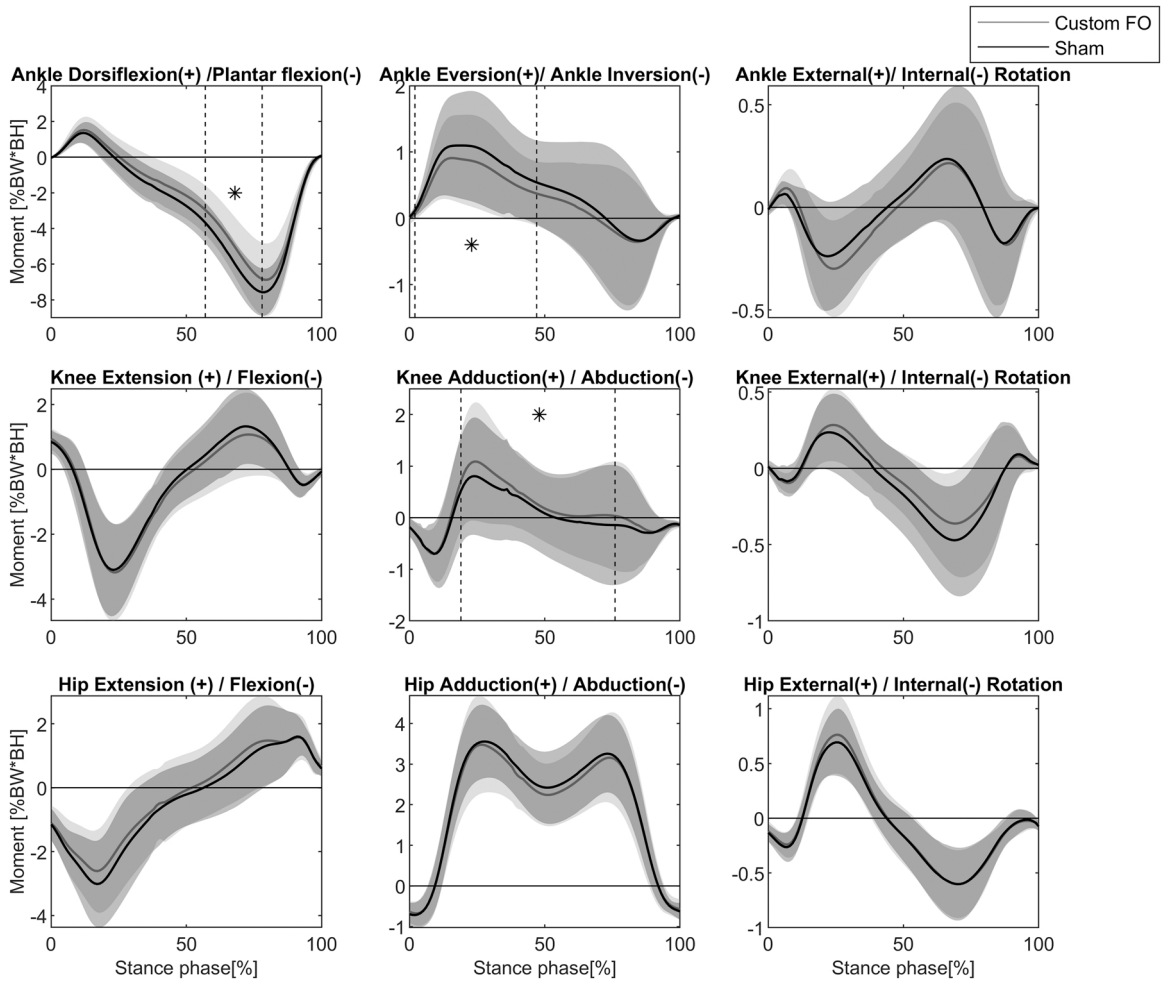

Fig. 5. Mean moments of the ankle, knee and hip joints. The black line is the control insole and the gray line is post-custom-made FO intervention. Statistical difference is the area between the dotted lines marked with a star.

tibialis posterior [30,31].

4.3. Daily activity levels and wearing time

Three months of FO intervention improved walking velocity in a 10 m walking test, in addition to reduced self-reported disability and pain [32]. No difference between activity levels was observed between the two periods in the present study, indicating that improvements in foot/ankle pain by custom-made FO not necessarily may lead to increased physical activity levels. A previous study has reported an average daily step count of 6000 for people with RA [33]. The present study observed an average of 10,000 daily steps, suggesting that this group was relatively physically active and, perhaps, had less capacity to increase daily steps even when pain is reduced. However, the present study's disease duration was lower compared to Katz et al. (2018) study (14.8 ± 12.3 years) [33].

It is common in clinical practice, to recommend a FO user to wear the insole as much as possible to maximize its possible benefits. Self-reported daily use has previously been reported around six days per week and 6 h per day [9]. The measured wearing time of the present study was comparable to the findings of Woodburn et al. who also found reduced foot pain in their study [9]. Therefore, we believe that the study participants used the FO adequately to achieve a pain-relieving effect. No linear relationship was found between wearing time and foot/ankle pain relief. This lack of relationship could indicate that either the relationship is not linear or a threshold where further use of FO does not result in additional pain relief at the foot/ankle. However, a larger sample is required to explore further this issue.

4.4. Strengths and limitations

Even though the present study was not an effectiveness study, the participants were not informed that the first period was a control. However, it was not difficult to tell the difference between the control and custom-made FO since they are different in physical appearance. The order of the control period and FO intervention was not blinded or randomized in the present study. However, the ankle/foot pain intensity was stable between the baseline and control measurements. These findings indicate that the participants had reached a pain plateau during the control period before starting the custom-made FO period. The present study's follow-up period was short but consistent with previous custom FO studies of participants with RA [24]. Unfortunately, pain ratings were not monitored during the two periods. It would be interesting to see if and when the participants began to experience pain relief. This relationship is essential to determine washout-periods lengths for this type of study. The foot was modelled as a single segment. Therefore, it was not possible to investigate potential biomechanical changes in the foot apart from the ankle joint complex. Moreover, disease activity was only measured once, therefore, it has not been possible to take disease flares into account. However, the inclusion criteria of stable disease phase and no pharmacological management changes, help assuring a stable disease phase during the study. Finally, only the right leg was measured. A previous study has shown that FO's effect on lower limb joint moments could differ between dominant and non-dominant side

[34]. Therefore, differences between dominant non-dominant could have been overlooked in the present study.

The present study provides new information about the effect of a custom-made FO on gait biomechanics, pain, and physical activity among people with RA. Reduced ankle plantar flexion moment and eversion moment during the stance phase was observed with the custom-made FO compared to the control. Reducing these moments might be advantageous for people with RA due to the relationship between RA and ankle tendon dysfunction. Even though the participants were in a stable disease phase with a short history of RA, there was still a significant decrease in foot/ankle pain intensity, which would potentially be more pronounced with higher disease severity.

The custom-made FO intervention reduced pain intensity, ankle plantar flexion, and eversion moments in people with RA. Adherence and changes in pain intensity were not correlated, and no difference in daily activity was observed between the control and the intervention period. The present study adds to a better understanding of mechanisms behind FO. However, more information at the individual patient level is required to optimize FO design that successfully target unloading, muscle function, gait kinematics and kinetics for the individual patient. Future research should focus on the interaction between FO design, pain relief, and altered biomechanics. This could be achieved by obtaining a more detailed description of the patients' changes in pain both in terms of location and pain intensity combined with detailed studies of altered biomechanics using computational modelling approaches. Thereby, aiding in identifying which FO design is optimal for specific types and locations of pain. Insights into this relationship can optimize FO treatment for people with RA.

Conflict of interest

The authors have no real or perceived financial and personal relationships with other people or organizations that could inappropriately influence (bias) our work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations.

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