Gait & Posture 95 (2022) 93–99

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Effect of customised preformed foot orthoses on gait parameters in children with juvenile idiopathic arthritis: A multicentre randomised clinical trial☆

Antoni Fellas [a,*], Davinder Singh-Grewal [b,c,e], Jeffrey Chaitow [b], Derek Santos [d], Matthew Clapham [f], Andrea Coda [a]

[a] School of Health Sciences, Faculty of Health and Medicine, University of Newcastle, Australia
[b] The Sydney Children's Hospital Network Randwick, and Westmead, Australia
[c] University of Sydney Discipline of Paediatrics and Child Health, Sydney, Australia
[d] School of Health Sciences, Queen Margaret University, Edinburgh EH21 6UU, UK
[e] University of New South Wales, School of Women's and Children's Health, Australia
[f] Hunter Medical Research Institute, Newcastle, Australia

ARTICLE INFO

Keywords:
Gait
Juvenile idiopathic arthritis
JIA
Paediatrics
Foot orthoses
Plantar pressure

ABSTRACT

Background: Children with juvenile idiopathic arthritis (JIA) can experience significant physical impairment of the lower extremity. Prolonged joint disease and symptoms may cause gait alterations such as reduced walking speed and increased plantar pressures in diseased areas of their feet. There is limited robust clinical trials investigating the effect of non-invasive mechanical therapies such as foot orthoses (FOs) on improving gait parameters in children with JIA.

Research question: Are customised preformed FOs effective in improving gait parameters in children with JIA?

Methods: A multicentre, parallel design, single-blinded randomised clinical trial was used to assess the gait impacts of customised preformed FOs on children with JIA. Children with a diagnosis of JIA, exhibiting lower limb symptoms and aged 5–18 were eligible. The trial group received a low-density full length, Slimflex Simple device which was customised chair side and the control group received a sham device. Peak pressure and pressure time integrals were used as the main gait outcomes and were measured using portable Tekscan gait analysis technology at baseline, 3 and 6 months. Differences at each follow-up were assessed using the Wilcoxon rank sum test.

Results: 66 participants were recruited. Customised preformed FOs were effective in altering plantar pressures in children with JIA versus a control device. Reductions of peak pressures and pressure time integrals in the heel, forefoot and 5th metatarsophalangeal joint were statistically significant in favour of the trial group. This was associated with statistically significant increased midfoot contact with the trial device at baseline, 3 and 6-month data collections. The trial intervention was safe and well accepted by participants, which is reflected in the high retention rate (92%).

Significance: Clinicians may prescribe customised preformed FOs in children with JIA to deflect pressure from painful joints and redistribute from high pressure areas such as the rearfoot and forefoot.

1. Introduction

Juvenile idiopathic arthritis (JIA) is the most prevalent rheumatic condition in children and adolescents, with active lower limb joint disease a common clinical manifestation [1]. Lower limb problems in JIA can lead to significant disturbances in gait, causing functional impairment and disability [2–10]. A recent study recorded this compensation pattern in both the initial contact and terminal stance phases of gait, despite the low pain and disease activity scores in their JIA cohort [11]. This suggests that even in the absence of active disease, children with

Abbreviations: JIA, Juvenile idiopathic arthritis; PP, peak pressure; PTI, pressure time integrals; RCT, randomised clinical trial; FOs, foot orthoses; EVA, ethylene-vinyl acetate; kPa, kilo pascals; MPJ, metatarsophalangeal joint.

☆ **Trial registry:** Australian New Zealand Clinical Trials Registry (ANZCTR): 12616001082493.

* Corresponding author.
E-mail address: Antoni.Fellas@uon.edu.au (A. Fellas).

https://doi.org/10.1016/j.gaitpost.2022.04.017
Received 6 July 2021; Received in revised form 9 April 2022; Accepted 18 April 2022
Available online 19 April 2022

JIA may still exhibit altered gait parameters [11]. Moreover, children with JIA tend to walk more slowly compared to their healthy peers [3,5,12]. Altered gait in JIA may also lead to sub-optimal plantar pressure distribution [2,13,14]. One recent study with 50 participants with polyarticular JIA, showed significantly increased total peak pressure (PP) in all areas of the foot except the 2nd and 5th toe regions, and significantly increased pressure time integrals (PTI) of the total foot compared to age and sex matched children [2]. Elevated PP and PTI may exacerbate already symptomatic areas of the feet causing further pain and physical impairment.

Recent research has demonstrated the need for targeted interventions to improve gait parameters, and in turn, maintain healthy physical function in children with JIA [2,3,8,11]. To our knowledge, two previous randomised clinical trials (RCT) has investigated the effect of foot orthoses (FOs) on gait parameters in JIA [15,16]. Coda et al. [15] used customised FOs prescribed at chair side. The study showed statistically significant results in favour of the trial group for improving gait and stance time, and the reduction of PP (total contact, heel, 5th metatarsal and distal phalanx) [15]. Powell et al. [16] used custom-moulded FOs and measured speed of ambulation as one of the secondary outcomes. Their results showed walking speed was significantly improved in the trial group. The results suggest that FOs can mitigate altered gait parameters; however, further clinical trials are needed to determine clinical significance for each gait parameter in children with JIA. Therefore, the aim of this study is to investigate the effect of customised preformed FOs on gait parameters such as PP and PTI in children with JIA.

2. Methods

The protocol has been published and available as open access (https://doi.org/10.1136/bmjpo-2017-000121) [17]. Gait parameter data collection deviated from protocol due to different gait equipment being utilised to collect information. Moreover, there was the addition of the pGALS and foot posture index validated measures of childhood lower limb biomechanics to aid description of participant's lower limb biomechanics at baseline. The changed gait parameters and assessments are outlined within the baseline and outcome measures.

2.1. Design

A prospective, parallel-group, single-blinded RCT.

2.2. Participants

Participants were recruited from the Sydney Children's Hospitals Network (Westmead and Randwick), and the John Hunter Children's Hospital (Newcastle). Table 1 displays the eligibility criteria for participants. Potentially eligible participants were identified by paediatric rheumatologists DSG and JC. Verbal and written informed consent was obtained from participants and where necessary parents. Once informed consent was acquired, participants were randomly assigned to receive either a control or trial intervention. The sequence generation was completed using a computer randomisation table by a researcher who was independent of participant recruitment and data collection (AC). The sequence was randomised in blocks of 10 and kept in individually sealed and opaque envelopes. Sealed envelopes were opened by the principal researcher (AF) on the day of participants baseline consultation to reveal their allocated intervention group. Participants were not informed what intervention group they were allocated to.

Table 1
Inclusion and exclusion criteria for enroling participants.

Inclusion	Exclusion
• Diagnosis of JIA according to the International League of Associations for Rheumatology criteria • Aged 5–18 years • active involvement of the lower limb (must include at least foot/and or ankle • No previous use of FOs or previous failure of foot orthotic management where the patient has not worn any FOs for a period of at least 3 months • If disease-modifying antirheumatic drugs and/or biological therapy are used, not having started these drug therapies within 6 months of enroling in the trial	• Currently using FOs • Inability to walk barefoot or shod for 15 m without assistive devices • Concomitant musculoskeletal disease • Central or peripheral nerve disease and endocrine disorders, including diabetes mellitus • History of lower limb surgery that required general anaesthetic • Where prescription of FOs is contraindicated, for example, significant osseous abnormalities noted in the lower limbs and/or vertebrae during the physical evaluation. • Unwillingness to wear appropriate footwear for fitting orthoses

2.3. Biomechanical assessment

Biomechanical measurements and careful physical examination of joints and associated muscles and tendons were obtained prior to prescription of the trial and control FOs. Principal researcher (AF) conducted all biomechanical assessments and prescription of FOs across all hospital sites. Validated assessments included paediatric gait arms legs spine assessment and the foot posture index-6 [18]. Additional observations which have not been validated in the paediatric population were recorded to aid orthoses prescription. These included visualising inspecting the movement of navicular during foot supination and pronation and the amount of rear foot eversion during stance. The average time taken to conduct a full biomechanical assessment prior to FOs prescription was 15 min.

2.4. Intervention group

Following the biomechanical assessment, devices were fitted on the same day of the initial consultation (baseline). Participants in both groups received standardised verbal education on appropriate footwear. Education on footwear was focused on explaining good supportive features of a shoe including a firm heel counter and rigid shank. Quality cushioning in the forefoot and rearfoot was also recommended. Lastly, the importance of footwear that contain adequate spacing in the shoe to allow proper fitting of the device, preferably those with removable liners. The trial group received customised, preformed FOs. The preformed device (SlimFlex Simple, Algeos PTY ltd) was full-length and made from low-density (PE30; 28–36 kg/m^3) ethylene-vinyl acetate (EVA), which was customised during the initial consultation according to the biomechanical need of each participant. Four main chair side modifications were prescribed:

1. EVA rearfoot anti-pronatory varus wedges of 3.5° or 5° degrees;
2. Plantar deflections (made from 6.4 mm poron) was used to offload any symptomatic joints;
3. Arch fill (made from 3.2 mm poron) to improve plantar pressure distribution or to support excessive midfoot pronation;
4. Full-length layer of cushioning (1.6 mm poron) was added to provide general shock absorption.

2.5. Control group

The control group received a standard flat insole, made from 1 mm leather board and with no corrective modifications. The top cover of the trial and control FOs were the same 'Dual Opulex Performance' 1.5 mm thick material made of neoprene and a 0.02 mm laminated 4-way stretch nylon top.

2.6. Adherence

Adherence to interventions was measured by asking participants to

record in a 'foot orthoses diary'. Participants were required to record daily usage per week for the duration of the trial. Written and verbal information were provided regarding how to use the devices. Participants were also informed to report to the principal researcher if any issues arose.

2.7. Outcome measures

Gait parameter outcomes were collected at baseline, 3 and 6 months. The primary outcomes for gait parameters in this trial were PP and PTI obtained from plantar pressure mapping of both feet at 10 standardised anatomical areas of the feet (Fig. 1) [19,20]. PP were measured in kilo Pascals (kPa) and PTI measured in kPa per seconds (kPa/s). PP is defined as the highest pressure value recorded by each sensor over the entire period of the stance phase [21]. PTI is measured as the amount of pressure detected over a period of time [21]. Secondary outcomes measures included: cadence (steps/min); stance time (s); swing time (s).

2.8. Procedure

All gait parameters were obtained using the latest Wireless F-Scan (Version 7.50-07) and HR Mat (Version 7.1-10) (Tekscan, Boston, USA), which are reliable in the paediatric population [19,20]. The F-Scan enables in-shoe analysis using high-resolution sensors inside footwear. The HR Mat is a validated platform designed to accurately record barefoot analysis. To increase reliability of HR Mat recordings, the validated 'two steps before striking the mat and two steps after' approach was used for every recording [22]. All participants wore the same Clark™ footwear as 'testing' shoes only during gait analysis recordings. Practice attempts were conducted prior to recordings to ensure participants were familiar in using the system. The sequence of recordings (shod, with device, barefoot) were randomised to limit the influence of gait variabilities due to symptomatic gait and/or attention deficit or boredom. Recordings for shod, shoes with FOs and barefoot were captured three times each per research session then averaged to give a more reliable measurement [23,24].

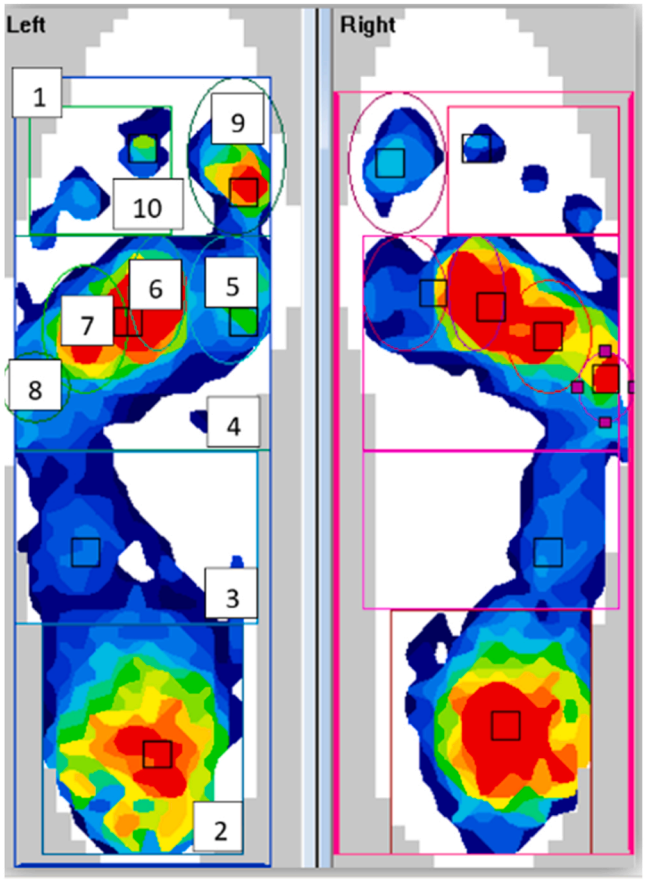

Fig. 1. Shows the 10 segmented plantar pressure map used to extrapolate data for both in-shoe and barefoot analysis. Area: 1 = Total; 2 = Heel; 3 = Midfoot; 4 = Forefoot; 5 = 1st MPJ; 6 = 2nd MPJ; 7 = 3rd/4th MPJs; 8 = 5th MPJ; 9 = Hallux; 10 = Lesser Toes.

2.9. Sample size

The sample size was calculated based on the primary outcome for this clinical trial (pain) [17]. The power calculation produced 30 participants per intervention group (30 trial and 30 control), with an overpowered total of 66 participants to allow for a 10% withdrawal rate.

2.10. Statistical analysis

All statistical analyses were designed by the study's biostatistician MC and programmed using Stata v14.0 (StataCorp Ltd, College Station, TX). Participants characteristics at baseline were compared descriptively by treatment group with means and SD. Frequencies and percentages were used for categorical variables. PP and PTI were averaged over left and right feet and summarised with medians and interquartile ranges at baseline, 3 and 6 months. Differences at baseline, 3 and 6 months were assessed with Wilcoxon's rank sum test. Coefficients are based on the trial group's data compared to the control. Negative coefficients means participants in the trial group experienced reduced kPa compared to the control and vice versa. Cadence, stance and swing time were summarised with means and SD at baseline, 3 and 6 months. A linear mixed model was used to assess the impact of the intervention at each timepoint. Time as categorical, including baseline with a time by group allocation interaction were included.

3. Results

Sixty-six participants with JIA were recruited and evenly randomised to each group (Fig. 2). Baseline participant characteristics obtained as part of the broader clinical trial were obtained from participants at baseline and are presented in Table 2.

3.1. Adherence and withdrawals

Fig. 2 depicts the participant flow diagram. There were no adverse situations in the recording of gait parameters with Tekscan equipment. Moreover, adherence to intervention was successful, with participants in both groups reporting an average of at least 4 days per week of wear in their FOs diary. On average, the trial group wore their FOs 4.7 days a week, while the control group was slightly less at 4.4 days per week. The majority of participants wore their FOs during school hours and days. During the first 6-months in this clinical trial a total of five participants withdrew. One participant with extended oligoarticular subtype in the trial group withdrew due to reporting discomfort and blistering of skin due to the device. The participant was offered a consultation to rectify the problem, however, chose to withdraw from the study. Four participants were lost in the control group: three withdrew due to reporting discomfort with their FOs and informed the chief investigator they did not want to continue; and one was eventually withdrawn as they failed to return three communication attempts.

3.1.1. Medication changed

Table 3 presents the characteristics of participants who flared by treatment group and their medication changes.

3.1.2. F-scan

Due to the non-parametric distribution of plantar pressure data,

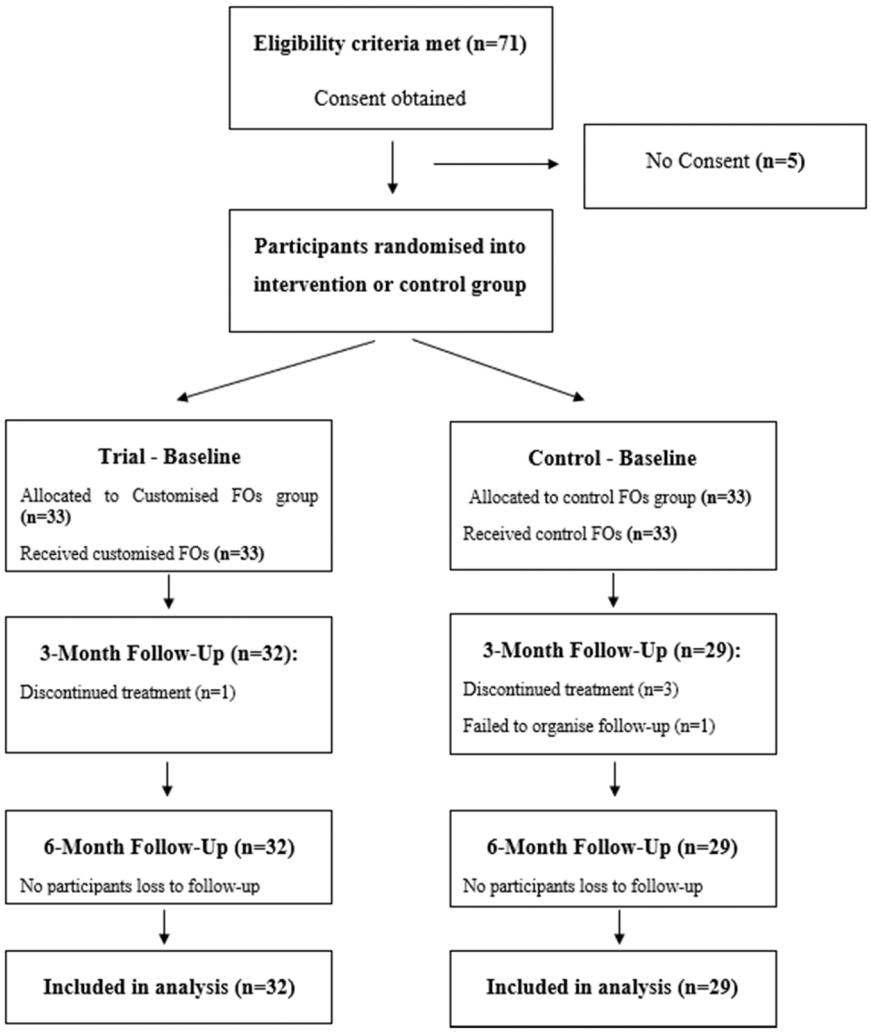

Fig. 2. Participant flow diagram.

medians and interquartile ranges were used and presented as a supplementary file.

For PP: the total at baseline (− 100.43 kPa, p = 0.034); heel at baseline (− 104.33 kPa, p = <0.001) and 3-months (− 126.16 kPa, p = 0.004); midfoot at baseline (29.84 kPa, p = 0.016), 3-months (24 kPa, p = 0.022) and 6-months (43.75 kPa, p = 0.036); forefoot at baseline (− 131.5 kPa, p = 0.027); 5th metatarsophalangeal joint (MPJ) at baseline (− 37.17 kPa, p = 0.007), 3-months (− 69.5 kPa, p = 0.001) and 6-months (− 50.91 kPa, p = 0.016); and 3rd/4th MPJs at 3-months (− 91.67 kPa, p = 0.034) were significantly different in favour of the trial group. There were no statistically significant differences between intervention groups for PP in the 2nd MPJ, 1st MPJ, lesser toes and hallux locations.

3.1.3. *Pressure time integrals*

For PTI: the total at 3-months (− 37.15 kPa/s, p = 0.035); heel at baseline (− 13.88 kPa/s, p = 0.038) and 3-months (− 19.29 kPa/s, p = 0.045); midfoot at baseline (6.78 kPa/s, p = 0.016), 3-months (9.69 kPa/s, p = 0.010) and 6-months (16.93 kPa/s, p = 0.026); forefoot at baseline (− 35.84 kPa/s, p = 0.021); and 5th MPJ at baseline (− 14.93 kPa/s, p = 0.048) were significantly different in favour of the trial group. There were no statistically significant differences between intervention groups for PTI in the 3rd/4th MPJs, 2nd MPJ, 1st MPJ, lesser toes and hallux locations.

3.1.4. *HR-Mat*

3.1.4.1. Peak pressure. Barefoot analysis for PP produced some statistically significant differences in favour of the trial group: the midfoot at 3-months (− 42.34 kPa, p = 0.011) and 6-months (− 61.42 kPa, p = 0.001); 5th MPJ at baseline (− 83.66 kPa, p = 0.020); 3rd/4th MPJs at baseline (− 85.5 kPa, p = 0.039). There were no statistically significant differences between intervention groups for PP in the total, heel, forefoot, 2nd MPJ, 1st MPJ, lesser toes and hallux locations.

3.1.5. *Pressure Time Integrals*

The midfoot was the only location that produced statistically significant differences between intervention groups for PTI. Similarly to PP for barefoot analysis, significant differences were detected at the midfoot at 3 (− 5.75 kPa/s, p = 0.030) and 6-month (− 11.23 kPa/s, p = 0.001) intervals.

All statistical analysis results for the ten plantar pressure areas collected with in-shoe and barefoot analysis are available in Table 4.

3.1.6. *Cadence, stance and swing time*

Cadence, stance and swing time were not significantly different at any follow-ups between groups. Descriptive and statistical results for cadence, stance and swing time are available as a supplementary file.

Table 2
Baseline participant characteristics.

Characteristic	Trial group n = 33	Control group n = 33
Demographics		
Age, years, mean (SD)	11.97 (3.83)	12.09 (3.40)
Male/female, n	10/23	11/22
Health Status		
VAS child reported pain, mean (SD)	48.33 (24.07)	42.12 (26.72)
PedsQL child reported QoL, mean (SD)	71.11 (16.06)	64.78 (15.04)
Duration of disease, years mean (SD)	6.70 (4.26)	6.29 (4.37)
Drug Therapies		
NSAIDS, n (%)	6 (18)	11 (33)
Analgesics, n (%)	1 (3)	0 (0)
Methotrexate, n (%)	15 (45)	17 (51)
Etanercept, n (%)	2 (6)	5 (15)
Adalimumab, n (%)	4 (12)	5 (15)
Tofacitinib, n (%)	1 (3)	1 (3)
Prednisone, n (%)	1 (3)	4 (12)
Tocilizumab, n (%)	4 (12)	3 (9)
Sulfasalazine, n (%)	1 (3)	1 (3)
Infliximab, n (%)	1 (3)	2 (6)
Leflunomide, n (%)	2 (6)	0 (0)
Combination Therapy-NSAID & Methotrexate or Biologic, n (%)	3 (9)	7 (21)
Combination Therapy-DMARD & Biologic, n (%)	5 (15)	5 (15)
ILAR Subtypes		
Persistent Oligoarticular, n (%)	4 (12)	7 (21)
Extended Oligoarticular, n (%)	9 (27)	8 (24)
Polyarticular RF -ve, n (%)	9 (27)	9 (27)
Polyarticular RF +ve, n (%)	3 (9)	1 (3)
Psoriatic, n (%)	2 (6)	1 (3)
Systemic, n (%)	2 (6)	2 (6)
Enthesitis-Related, n (%)	4 (12)	5 (15)
Undifferentiated, n (%)	0 (0)	0 (0)

SD: Standard deviation; VAS: Visual analogue scale; PedsQL: Paediatric quality of life; NSAID: non-steroidal anti-inflammatory drug; DMARD: disease modifying anti-rheumatic drug; ILAR; International League of Associations for Rheumatology.

3.2. Adjusted statistical analysis

An adjusted analysis was conducted for plantar pressure and gait parameter data to determine if changes in medication amongst participants impacted the outcome of results. Adjusted in-shoe analysis for PP resulted changes in statistical significance to total at baseline, heel at 3 months, forefoot at baseline, 5th MPJ at 6-months and 3rd/4th MPJs at 3-months. Four changes were noted in the PTI for in-shoe analysis: total at 3-months, heel at baseline and 3-months, forefoot at baseline and 5th MPJ at baseline. For HR-Mat, three outcomes were no longer statistically significant when adjusting for medication changed participants in PP outcomes: midfoot at 3-months, 5th MPJ at baseline and 3rd/4th MPJs at baseline. One change to PTI data was noted with midfoot at 3-months showing insignificant differences.

4. Discussion

4.1. Primary findings

Plantar pressure data displayed non-parametric distributions and was analysed using Wilcoxon tests. Analysis showed statistically significant differences in favour of the trial group in multiple locations of the plantar foot. Increasing pressure through the medial longitudinal arch of the feet with FOs can distribute pressure from high contact and painful pressure areas, such as the rearfoot and forefoot. This was evident in our clinical trial with statistically significant differences in the reduction of PP and PTI in the heel and forefoot locations with statistically significant increased PP and PTI of the midfoot. Heel pressure was statistically significant in favour of the trial group with a reduction of PP of 100.34 kPa at baseline ($p = < 0.001$) and 126.33 Pa 3-months ($p = 0.004$). The 6-month follow-up was not statistically significant which could be explained by degrading of lower density materials by the 6-month follow-up. Interestingly, the outcome of pain (presented elsewhere) was also only statistically significant in the reduction of pain in favour of the trial group in the first 3 months but not at the 6-month follow-up [25]. The reduction of forefoot pressures was only statistically different in favour of the trial group at baseline for both PP and PTI. However, the 5th MPJ showed statistically significant differences in the reduction of PP at all timepoints. The PTI were also significantly reduced at baseline and 3-months for the 5th MPJ.

Participants in the trial group exhibited significantly less midfoot contact when walking barefoot compared to participants in the control group. This change was detected at the 3 and 6-month follow-ups for both PP and PTI. This suggests a possible residual mechanical effect or neuromuscular adaptive response on the midfoot from wearing the customised preformed FOs [26]. It is possible that statistically significant differences in midfoot contact was not detected at baseline, as participants required time for this residual effect to occur. Lastly, results showed no statistically significant results for cadence, swing and stance time gait parameters. There was a trend for an increased cadence at the 6-month follow-up in favour of the control group, but this was not statistically significant.

This is the second RCT that has found statistically significant differences in favour of the trial group in altering gait patterns in children

Table 3
Participant medication changes by treatment group.

	Trial					Control			
	Subtype	Joint Flare	Follow-up	Medication change		Subtype	Joint Flare	Follow-up	Medication change
Participant 1	Polyarticular -ve	Midfoot joints	3-month	Medication replacement + joint injection	Participant 1	Extended Oligoarticular	Knee and ankle	3-month	Medication replacement + joint injections
Participant 2	Extended Oligoarticular	Knee + ankle	6-month	Joint injections	Participant 2	Polyarticular -ve	Upper and lower limb joints	3-month	Medication added
Participant 3	Polyarticular -ve	Knee + ankle	6-month	Joint injections	Participant 3	ERA	Hip	6-month	Medication added
Participant 4	Polyarticular -ve	Ankle	6-month	Joint injection	Participant 4	Polyarticular -ve	Ankle	6-month	Medication added + joint injection
Participant 5	Polyarticular -ve	Upper and lower limb joints	6-month	Medication added	Participant 5	ERA	Knee + ankle	6-month	Medication added

ERA: enthesitis-related arthritis; -ve: negative.

Table 4
Statistical analysis results for F-scan and HR-Mat data.

Outcomes		F-SCAN				HR MAT			
		Peak pressure		Pressure time integrals		Peak pressure		Pressure time integrals	
		Coef.	P > |z|	Coef.	P > |z|	Coef.	P > |z|	Coef.	P > |z|
Total									
	Baseline	-100.34	0.034*	-30.04	0.057	-36	0.456	-22.81	0.394
	3-Month	-126.33	0.07	-37.15	0.035*	-1.66	0.430	-5.06	0.916
	6-Month	-64.42	0.471	-6	0.413	36.09	0.502	-14.72	0.806
Heel									
	Baseline	-104.33	< 0.001**	-13.88	0.038*	26.33	0.559	-0.25	0.624
	3-Month	-126.16	0.004*	-19.29	0.045*	15.34	0.243	7.66	0.355
	6-Month	-51.66	0.203	-17.17	0.286	77.08	0.883	21.84	0.512
Midfoot									
	Baseline	29.84	0.016*	6.76	0.016*	-32.33	0.138	-4.97	0.113
	3-Month	24	0.022*	9.69	0.010*	-42.34	0.011*	-5.75	0.030*
	6-Month	43.75	0.036*	16.93	0.026*	-61.42	0.001*	-11.23	0.001*
Forefoot									
	Baseline	-131.5	0.027*	-35.84	0.021*	-73.84	0.149	-36.7	0.262
	3-Month	-102.33	0.103	-24.15	0.056	2.17	0.820	-30.57	0.544
	6-Month	-5.16	0.413	-20.03	0.131	-37.67	0.883	-42.35	0.441
5th MPJ									
	Baseline	-37.17	0.007*	-14.93	0.048*	-83.66	0.020*	-24.39	0.100
	3-Month	-69.5	0.001*	-12.01	0.016*	2.34	0.722	-12.18	0.340
	6-Month	-50.91	0.016*	-16.49	0.075	-20	0.909	-11.94	0.385
3rd/4th MPJ									
	Baseline	-90.5	0.051	-23.52	0.059	-85.5	0.039*	-21.29	0.145
	3-Month	-91.67	0.034*	-16.73	0.075	3.42	0.820	-15.79	0.303
	6-Month	-21.34	0.302	-8.58	0.200	-11.25	0.682	-19.43	0.303
2nd MPJ									
	Baseline	-56	0.132	-29.42	0.079	-59.17	0.286	-12.73	0.351
	3-Month	-22.84	0.333	-6.08	0.241	9.83	0.838	2.9	0.928
	6-Month	18.75	0.769	-4.89	0.294	14.5	0.706	-13.59	0.974
1st MPJ									
	Baseline	-8.17	0.236	-4.2	0.243	5.34	0.727	-12.94	0.292
	3-Month	-18.5	0.389	-3.68	0.456	38.91	0.628	15.01	0.773
	6-Month	-14	0.842	-3.56	0.406	-17.25	0.712	-3.09	0.743
L-Toes									
	Baseline	-5.66	0.644	0.3	0.913	17	0.914	1	0.705
	3-Month	17.66	0.283	4.81	0.475	-15.5	0.715	-1.9	0.988
	6-Month	8.25	0.150	8.22	0.186	-13.75	0.475	-1.89	0.422
Hallux									
	Baseline	32.5	0.944	2.12	0.813	26	0.344	9.61	0.402
	3-Month	11	0.594	-1.85	0.646	15.41	0.343	9.22	0.375
	6-Month	29.16	0.583	7.11	0.681	53.92	0.154	0	0.700

MPJ: metatarsal phalangeal joint; L-Toes: Lesser Toes; Coef.: coefficient; P > |z|: p-value; * $p < 0.05$, ** $p < 0.001$. The coefficient values reflect the average increase or decrease of the trial groups kPa (peak pressure) or kPa/s (pressure time integrals) in relation to the control.

with JIA. However, only Coda et al. [15] produced statistically significant differences of increased pressure under the hallux in favour of the trial group. Coda et al. [15] also opted for the Slimflex Plus' which are made of higher density EVA (50 shore), compared to the lower density EVA (30 shore) 'Slimflex Simple' used in this clinical trial. Medium density materials are typically firmer and are more durable at maintaining structural integrity over a prolonged period of time, therefore, there may be a need for more functional rearfoot and midfoot control rather than providing shock absorption.

4.2. Limitations

The sample size calculation was based on pain, which was the primary outcome of the broader clinical trial [17]. While the sample size was not calculated specifically for gait data, it is recommended by the CONSORT statement to power your sample size based on the primary outcome. A post-hoc power analysis was conducted to estimate the required sample size based on the F-scan peak pressure means and standard deviations at baseline, 3 and 6 months. The analysis estimated that an equal group of 135 participants would be required for 80% power at the 5% significance level. This suggests the sample size used in this study was not adequate to detect significance in gait parameter data for all follow-ups. Adjusted statistical analysis suggests changes in medication and disease status may have impacted the results of this clinical trial. Participants experiencing a flare and subsequently requiring a change in medication were removed in a secondary data set. This data set reduced the number of statistically significant differences between groups. However, it is unclear if this sub-group analysis produced less significant differences due to no medication/disease changes or insufficient sample size. Despite a lower sample size in the adjusted data set, areas of the plantar foot such as the heel, midfoot and 5th MPJ remained statistically significant in favour of the trial group.

4.3. Recommendations for future research and clinical practice

If children with JIA are exhibiting sub-optimal plantar pressure patterns, then clinicians can use customised preformed FOs to mitigate high PP and improve biomechanical function. If clinicians do not have access to gait analysis technology, then basic clinical assessments such as a joint examination, biomechanical testing and screening for excessive hyperkeratotic formation can be useful to identify altered plantar patterns. For example, if patients with JIA are excessively pronated in the midfoot and present with hyperkeratotic patterns across their lesser MPJs, this may suggest low gear propulsive biomechanics. In this case, a customised preformed device can be effective in supporting the midfoot to reduce excessive midfoot pronation and encourage instigation of the

windlass and subsequently less PP in the lateral forefoot. Currently, no RCTs have explored the long-term effect of customised preformed FOs on plantar pressure and gait parameter outcomes in children with JIA. Future trials should follow-up gait outcomes beyond 6 months and include group comparisons of different densities in devices to determine if the density of the preformed device significantly impacts on improving gait parameters in children with JIA.

5. Conclusion

Customised preformed FOs were effective in altering plantar pressures in children and adolescents with JIA. The trial group exhibited statistically significant increased midfoot pressures which resulted in significantly less rearfoot and forefoot pressures compared to the control group. Clinicians can introduce this inexpensive intervention to mediate altered plantar pressures which can be common in JIA children with foot and ankle disease. Overall, the trial intervention was safe, accessible and easily translated to a clinical setting at low cost to health care providers and patients.

CRediT authorship contribution statement

All authors contributed to the overall design of the study. **DSG** and **JC** were responsible for identifying potentially eligible participants, and **AF** recruited them in the trial. **AC** was responsible for sequence generation and sealing treatment allocation in opaque envelopes. **AF** conducted biomechanical testing and prescription of the trial and control intervention. **AF** completed all gait analysis data collection across all three outpatient locations. **MC** was the biostatistician for this clinical trial and was responsible for designing the statistical analysis. All authors drafted the manuscript, critically revised the article for important intellectual content, and provided final approval of the submitted version.

Funding

The University of Newcastle, Australia (part of Ph.D. scholarship).

Patient consent

Obtained.

Ethics approval

Hunter New England Human Research Ethics Committee (16/09/21/4.03). Site authorisation was approved for all data collection sites by the relevant research governance committees.

Declaration of Competing Interest

All authors declare no conflicts of interest. All research equipment, FOs and materials were paid in full through Mr. Antoni Fellas' Ph.D. funding.

Acknowledgements

The research team would like to thank all participants and parents for their time and important contribution to this clinical trial. We would also like to extend our sincerest gratitude to the outpatient teams at the Sydney Children's Hospital at Westmead and Randwick and the John Hunter Children's Hospital for accommodating this clinical trial in their already busy clinics.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.gaitpost.2022.04.017.

References

[1] A. Ravelli, A. Martini, Juvenile idiopathic arthritis, Lancet 369 (9563) (2007) 767–778.
[2] J. Merker, M. Hartmann, J.-P. Haas, A. Schwirtz, Combined three-dimensional gait and plantar pressure analyses detecting significant functional deficits in children with juvenile idiopathic arthritis, Gait Posture 66 (2018) 247–254.
[3] J. Merker, M. Hartmann, F. Kreuzpointner, A. Schwirtz, J.-P. Haas, Pathophysiology of juvenile idiopathic arthritis induced pes planovalgus in static and walking condition—a functional view using 3d gait analysis, Pediatr. Rheumatol. 13 (1) (2015) 21.
[4] E. Broström, M. Örtqvist, Y. Haglund-Åkerlind, S. Hagelberg, E. Gutierrez-Farewik, Trunk and center of mass movements during gait in children with juvenile idiopathic arthritis, Hum. Mov. Sci. 26 (2) (2007) 296–305.
[5] E. Brostrom, Y. Haglund-Akerlind, S. Hagelberg, A.G. Cresswell, Gait in children with juvenile chronic arthritis. Timing and force parameters, Scand. J. Rheuma 31 (6) (2002) 317–323.
[6] D.E. Lechner, C.F. McCarthy, M.K. Holden, Gait deviations in patients with juvenile rheumatoid arthritis, Phys. Ther. 67 (9) (1987) 1335–1341.
[7] H. Truckenbrodt, R. Häfner, Functional joint analysis of the foot in juvenile chronic arthritis, Clin. Exp. Rheumatol. 12 (1994) S91–S96.
[8] M. Hartmann, F. Kreuzpointner, R. Haefner, H. Michels, A. Schwirtz, J. Haas, Effects of juvenile idiopathic arthritis on kinematics and kinetics of the lower extremities call for consequences in physical activities recommendations, Int. J. Pediatr. 2010 (2010).
[9] C. Frigo, M. Bardare, F. Corona, D. Casnaghi, R. Cimaz, P.N. Fovino, et al., Gait alteration in patients with juvenile chronic arthritis: a computerized analysis, J. Orthop. Rheumatol. 9 (2) (1996) 82–90.
[10] L. Woolnough, A. Pomputius, H.K. Vincent, Juvenile idiopathic arthritis, gait characteristics and relation to function, Gait Posture 85 (2021) 38–54.
[11] G. Kuntze, C. Nesbitt, A. Nettel-Aguirre, S.E. MKin, R. Scholz, J. Brooks, et al., Gait adaptations in youth with juvenile idiopathic arthritis, Arthritis Care Res. (2019).
[12] G.J. Hendry, D. Rafferty, R. Barn, J. Gardner-Medwin, D.E. Turner, J. Woodburn, Foot function is well preserved in children and adolescents with juvenile idiopathic arthritis who are optimally managed, Gait Posture 38 (1) (2013) 30–36.
[13] M. Orlin, K. Stetson, J. Skowronski, M. Pierrynowski, Foot pressure distribution: methodology and clinical application for children with ankle rheumatoid arthritis, Clin. Biomech. 12 (3) (1997). S17-S17.
[14] M. Dhanendran, W. Hutton, L. Klenerman, S. Witemeyer, B. Ansell, Foot function in juvenile chronic arthritis, Rheumatology 19 (1) (1980) 20–24.
[15] A. Coda, T. Carline, D. Santos, Foot Orthoses in Children with Juvenile Idiopathic Arthritis (JIA), Lambert Academic Publishing, 2015.
[16] M. Powell, M. Seid, I.S. Szer, Efficacy of custom foot orthotics in improving pain and functional status in children with juvenile idiopathic arthritis: a randomized trial, J. Rheumatol. 32 (5) (2005) 943–950.
[17] A. Fellas, D. Singh-Grewal, J. Chaitow, D. Santos, A. Coda, Effectiveness of preformed foot orthoses in reducing lower limb pain, swollen and tender joints and in improving quality of life and gait parameters in children with juvenile idiopathic arthritis: a randomised controlled trial (Protocol), BMJ Paediatr. Open 1 (1) (2017), e000121.
[18] A.M. Evans, K. Rome, L. Peet, The foot posture index, ankle lunge test, Beighton scale and the lower limb assessment score in healthy children: a reliability study, J. Foot ankle Res. 5 (1) (2012) 1–5.
[19] A. Coda, D. Santos, Repeatability and reproducibility of the F-scan system in healthy children, J. Orthop. Rheumatol. Sports Med. 1 (1) (2015) 104.
[20] A. Coda, T. Carline, D. Santos, Repeatability and reproducibility of the Tekscan HR-Walkway system in healthy children, Foot 24 (2) (2014) 49–55.
[21] M.N. Orlin, T.G. McPoil, Plantar pressure assessment, Phys. Ther. 80 (4) (2000) 399–409.
[22] G.V. Zammit, H.B. Menz, S.E. Munteanu, Reliability of the TekScan MatScan® system for the measurement of plantar forces and pressures during barefoot level walking in healthy adults, J. Foot Ankle Res. 3 (1) (2010) 11.
[23] J. Hughes, L. Pratt, K. Linge, P. Clark, L. Klenerman, Reliability of pressure measurements: the EM ED F system, Clin. Biomech. 6 (1) (1991) 14–18.
[24] M. van der Leeden, J.H. Dekker, P.C. Siemonsma, S.S. Lek-Westerhof, M. P. Steultjens, Reproducibility of plantar pressure measurements in patients with chronic arthritis: a comparison of one-step, two-step, and three-step protocols and an estimate of the number of measurements required, Foot Ankle Int. 25 (10) (2004) 739–744.
[25] A. Fellas, D. Singh-Grewal, J. Chaitow, D. Santos, M. Clapham, A. Coda, Effect of preformed foot orthoses in reducing pain in children with juvenile idiopathic arthritis: a multicentre randomized clinical trial, Rheumatology (2021).
[26] J. Duchateau, R.M. Enoka, Neural adaptations with chronic activity patterns in able-bodied humans, Am. J. Phys. Med. Rehabil. 81 (11) (2002) S17–S27.