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Effects of a 10-week footstrike transition programme on tibial stress fracture probability; a randomized controlled intervention using finite element and probabilistic modelling

Jonathan Sinclair
School of Health, Social Work and Sport, University of Central Lancashire, Preston, UK, jksinclair@uclan.ac.uk

Paul J. Taylor
University of Central Lancashire, Preston, UK, ptaylor@uclan.ac.uk

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Abstract

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Keywords

biomechanics, finite element analysis, musculoskeletal simulation, probabilistic modelling, footstrike

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Article

Effects of a 10-week footstrike transition programme on tibial stress fracture probability; a randomized controlled intervention using finite element and probabilistic modelling

Jonathan SINCLAIR[1], Paul J. TAYLOR[2]

[1] School of Health, Social Work and Sport, University of Central Lancashire, Preston, UK; ORCID 0000-0002-2231-3732
[2] University of Central Lancashire, Preston, UK; ORCID 0000-0001-8743-7667

* Correspondence: Dr Jonathan Sinclair, e-mail: jksinclair@uclan.ac.uk

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1. Introduction

Running, a widely accessible form of exercise, is linked to numerous physiological [1] and psychological [2] advantages. Nonetheless, it is also correlated with a significant prevalence of chronic injuries [3], affecting as many as 20–80% of runners annually [4]. Among these, bone stress fractures stand out as a prevalent chronic injury, constituting up to 30% of all musculoskeletal injuries related to running [5]. The tibia is consistently identified as the most susceptible site to stress fractures [6, 7], with around 74% of such incidents occurring there [8]. These fractures typically manifest in the anterior diaphyseal region of the tibia [5] and pose significant challenges due to their extended recovery period and heightened risk of recurrence [9].

Running, being a repetitive activity, subjects the skeletal system to continual loads, capable of initiating bone fatigue [10]. Strain is considered the main indicator of actual structural bone damage [11]. Since in-vivo strains during running are notably lower than bone's ultimate strength, stress fracture occurrences are viewed as manifestations of mechanical fatigue [12], often depicted through an inverse power law relationship [13]. Stress fractures develop due to the accumulation of microscopic damage within the bone matrix [14]. Allowing adequate rest between running sessions permits bone remodelling, potentially reinforcing bone integrity [15]. However, if damage accrual surpasses bone remodelling and adaptation rates, microcracks may emerge and evolve into stress fractures [16]. Notably, when the tibia experiences low strain levels, damage accumulation diminishes, affording the tissue more time to repair microcracks. Conversely, high strains surpass the repair and adaptation capacity [17]. Hence, identifying tibial loading patterns that reduce strain during running may assist in preventing stress fracture occurrences.

The concept of footstrike patterns in runners has received considerable attention in biomechanics literature [18]. Runners are categorized into one of three footstrike classifications on the basis of the position of their centre of mass relative to the foot at the instant of initial ground contact [19]: rearfoot strikers (in which initial contact with the ground occurs at the heel or posterior part of the foot), midfoot strikers (whereby the posterior and anterior portions of the foot simultaneously contact the ground), and forefoot strikers (where the anterior region of the foot strikes the ground first). It is well documented within the biomechanical literature that the majority of runners utilize a rearfoot strike pattern, with as many as 95% adopting this footstrike modality [20].

Tibial accelerations and the loading rate of the vertical ground reaction force (GRF) are frequently utilized as proxy indicators for tibial loading, and have long been proposed as potential contributors to the development of tibial stress fractures [21]. Substantial research interest has been directed towards exploring the effects of different footstrike patterns on tibial accelerations and the vertical loading rates during running. It has been observed that both habitual and converted non-rearfoot strike patterns are characterized by the absence of an impact peak in the vertical GRF [22–27] as well as reductions in vertical loading rates [23, 24, 27–34] and tibial accelerations [35,36] in comparison to a rearfoot strike, leading to the supposition that modifying the footstrike pattern away from a rearfoot strike may be an effective strategy to effectively reduce the risk for tibial stress fractures during running.

However, recent evidence has shown that surrogate measures, such as tibial acceleration and loading rates of the vertical GRF, are not representative of tibial bone loading in running [21]. Finite element modelling has been shown to provide more realistic estimates of in vivo tibial bone strains [37], directly linked to the aetiology of stress fractures [11], indicating that this technique can be utilized to make informed predictions of the damage potential. Significant advances in finite element analyses made in recent years now allow computational probabilistic modelling of the tibia to be undertaken [37] in order to quantify the probability of tibial stress fractures in runners utilizing different strike patterns. Indeed, Chen et al. [30] examined the immediate effects of transitioning the footstrike pattern away from a rearfoot contact position on tibial strains and stress fracture probability. Their observations showed no significant difference in tibial strains or risk of tibial stress fracture with different landing patterns. However, as this investigation explored the immediate effects of footstrike transition and did not feature a control group, there has yet to be a randomized intervention exploring the efficacy of a more prolonged and gradual footstrike transition, utilizing the aforementioned approaches.

Aim: The aim of this study is to undertake a randomized control trial examining the effects of a 10-week footstrike transition program compared to a control group, using a collective finite element analysis and computational probabilistic modelling-based approach. The primary objective of this trial is to examine the influence of the footstrike transition program on tibial stress fracture probability relative to control, and its secondary objectives are to examine running biomechanics, muscle forces, joint contact forces, and tibial strains.

Hypotheses: This investigation hypothesizes that transitioning from a rearfoot strike pattern will reduce tibial stress fracture probability in relation to the control group.

2. Material and Methods

2.1. Study design and setting

This examination comprises a parallel, randomized controlled trial spanning 10-weeks. The intervention period of 10 weeks adhered to the previously established guidelines [27], and the protocol was formulated based on the revised recommendations for reporting parallel group randomized controlled trials [38]. The University of Central Lancashire conducted the current investigation at their main campus located in Preston within the county of Lancashire, the United Kingdom. Following the eligibility screening and enrolment process, participants underwent individual randomization through a computer program (Random Allocation Software) into either control or footstrike groups. Primary and secondary outcome variables, as described in detail below, were assessed at baseline and after 10 weeks. The primary outcome measure was the between-group change in tibial stress fracture probability. The secondary outcome measures were between-group differences in running biomechanics, muscle forces, joint contact forces, and tibial strains.

Inclusion criteria: For inclusion in either the control or the footstrike groups, it was necessary for runners to be free of a running-related injury for at least three months, and to have no prior history of tibial stress fractures or tibial pain. In addition, all runners initially exhibited a rearfoot strike pattern which was verified by the presence of an impact peak in their vertical GRF curve [22] and also through individual examination of participant's sagittal plane ankle positions at foot strike [19]. Both groups were composed of participants of either sex, commonly running at least 10 km per week, and aged between 18 and 45 years.

Exclusion criteria: Runners with a current running or indeed any other type of lower extremity injury were ineligible for participation, as were any who did not exhibit a rearfoot strike running pattern.

Sample Size: Calculations for the sample size were not possible for the primary outcome as there has yet to be a randomized controlled trial examining the effects of footstrike transition tibial stress fracture probability nor is there an established minimum clinically important difference for tibial stress fractures. Therefore, a pragmatic sample size calculation, based on the findings of Chan et al. [34] for the between group difference in the loading rate of the vertical GRF following gait retraining was undertaken using G*Power 3.1 (Universität Kiel, Germany). This analysis yielded a d = 1.34 and indicated that a total sample size of 20 was needed to achieve a significance level of 5% and 80% power.

2.2. Ethical approval and registration

Approval for the study was granted by an institutional ethical review board (STEMH 381), and all participants submitted written informed consent before participating, adhering to the principles stated in the Declaration of Helsinki. The trial was preregistered on clinicaltrials.gov (NCT05786079).

2.3. Participants and recruitment

Recruiting materials were placed in running clubs and gymnasiums located in the Preston area of Lancashire using public bulletin boards. Individuals expressing interest in participation were provided with a chance to reach out to the research team for additional details about the study and to address any questions related to participation. Written informed consent was acquired, and all participants were instructed to continue their regular medication regimen. Participants in both groups were asked to maintain their current training volume until the completion of their final data collection session.

2.4. Intervention

Control: The control group (age = 35.60 ± 10.68 years, mass = 76.89 ± 10.68 kg, stature = 173.72 ± 9.58 cm, BMI = 25.15 ± 3.95 kg/m^2) were requested maintain their habitual running training regime and volume without any alterations to their running strike pattern.

Footstrike: Following initial data collection, each the footstrike group (age = 25.30 ± 2.98 years, mass = 69.55 ± 10.40 kg, stature = 170.55 ± 4.49 cm, BMI = 23.79 ± 2.13 kg/m^2) were given a structured programme of running with the aim of transitioning from their habitual rearfoot strike pattern, and exercises designed to reduce the likelihood of injury (Table 1). Instructions for changes in the running technique were provided taking into account and adapting where appropriate previous observations from biomechanics literature. Specifically, participants were instructed to 1) increase their cadence and decrease their stride length [39, 40], 2) run with light footfalls, landing on the ball of the foot [40, 41], and 3) keep the head up and run as tall as possible [39, 40]. The program allowed runners to continue their normal training load but increased the proportion of total mileage in which a non-rearfoot strike pattern was used by 10% each week, thus exposure to non-rearfoot strike running was gradually increased [40, 42]. Four strengthening exercises and four stretching exercises were provided to participants in order to prevent injury during the transition [40]; these were also introduced in a graduated manner.

Table 1. 10-week footstrike transition program details.

	Running distance	Exercises				Stretches			
Week	% of total running mileage	Bilateral heel raises	Balance diagonals	Single leg calf raise	Single limb balance (60's)	Wall calf stretch	Stair calf stretch	Plantar fascia roll	Calf roll
		Sets/ repetitions per day				Hold duration (s)/ reps		Duration (s)	
1	10	2 / 10	2 / 10	1 / 10	1 / 1	8s / 2	8s / 2	60	60
2	20	2 / 10	2 / 10	1 / 10	1 / 1	8s / 2	8s / 2	60	60
3	30	2 / 10	2 / 10	1 / 10	1 / 1	8s / 3	8s / 3	60	60
4	40	3 / 10	3 / 10	2 / 12	1 / 2	8s / 4	8s / 4	120	120
5	50	3 / 10	3 / 12	2 / 12	1 / 2	10s / 4	10s / 4	120	120
6	60	3 / 12	3 / 12	3 / 12	1 / 2	15s / 4	15s / 4	120	120
7	70	3 / 15	3 / 15	3 / 12	2 / 2	15s / 4	15s / 4	120	120
8	80	3 / 15	3 / 15	3 / 15	2 / 2	15s / 4	15s / 4	120	120
9	90	4 / 15	4 / 15	4 / 15	2 / 3	15s / 5	15s / 5	180	180
10	100	5 / 15	4 / 15	4 / 15	2 / 3	15s / 5	15s / 5	180	180

2.5. Data collection

Volunteers ran at a self-selected velocity through a 22-meter biomechanics laboratory, contacting an embedded piezoelectric force platform (Kistler Instruments Ltd., Winterthur, Switzerland) that recorded data at a frequency of 1000 Hz, with their right limb, (which was dominant in all participants). The stance phase of running was defined as the period during which the vertical GRF exceeded 20 N [43]. Each participant successfully completed five trials for each type of footwear, meeting the criteria of maintaining the specified velocity range, achieving complete foot contact with the force platform, and displaying no visible alterations in their gait due to the experimental conditions. Furthermore, to ensure that a consistent running velocity was obtained, the difference in the braking and propulsive acceleration portions of the anterior-posterior GRF were examined using a custom Matlab program (MATLAB, MathWorks, Natick, USA), and trials were rejected when this difference was more than 10% of the total rectified braking-propulsive GRF [44]. The order in which participants ran with each type of footwear was counterbalanced. Simultaneous kinematic and GRF data were collected, with kinematic data recorded at a rate of 250 Hz using an eight-camera motion analysis system (Qualisys Medical AB, Goteburg, Sweden). Prior to each data collection session, a dynamic calibration process for the motion capture system was performed.

The body segments were modelled with six degrees of freedom using the calibrated anatomical systems technique, as detailed by Cappozzo et al. [45]. To establish the anatomical frames for the thorax, pelvis, thighs, shanks, and feet, retroreflective markers were positioned at key bony landmarks, which included C7, T12, xiphoid process, iliac crest, anterior superior iliac spine (ASIS), posterior superior iliac spine (PSIS), medial and lateral malleoli, medial and lateral femoral epicondyles, greater trochanter, calcaneus, first metatarsal, and fifth metatarsal (Figure 1).

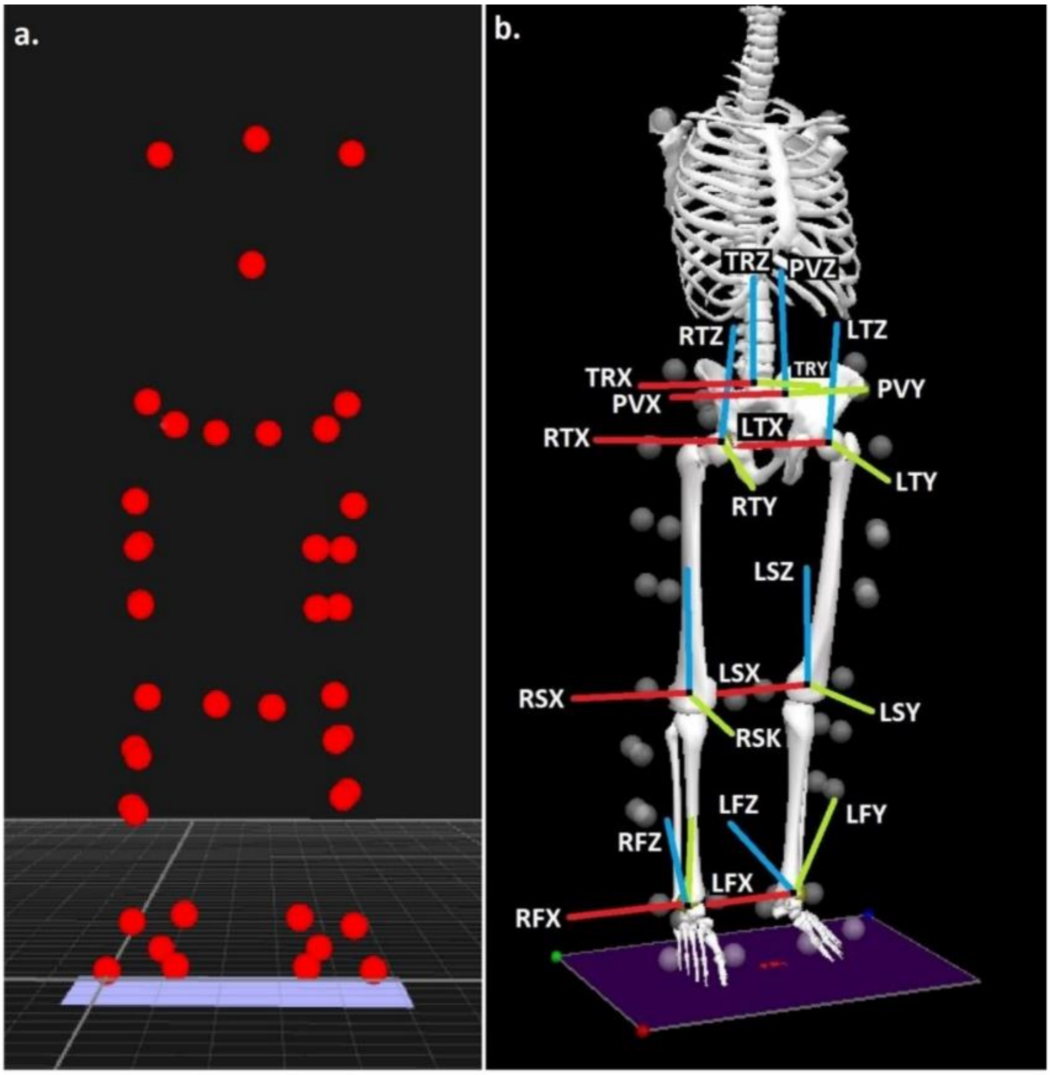

Figure 1. Experimental retroreflective marker positions (a) and (R = right & L = left, TR = trunk, P = pelvis, T = thigh, S = shank & F = foot, X = sagittal plane, Y = coronal plane & Z = trans-verse plane).

Tracking clusters, constructed from carbon fibre and equipped with four non-linear retroreflective markers, were securely attached to the thigh and shank segments using rigid sports tape. The foot segments were tracked using markers on the calcaneus, first metatarsal, and fifth metatarsal, the pelvic segment was tracked with the PSIS and ASIS markers, and the thorax segment was tracked using markers positioned at T12, C7, and the xiphoid process.

To establish references for anatomical markers in relation to tracking markers/clusters, static calibration trials were conducted. The centres of the ankle and knee joints were determined as the midpoints between the malleoli and femoral epicondyle markers [46, 47], whereas the centre of the hip joint was calculated using a regression equation based on the positions of the ASIS markers [48]. Each segment's Z (transverse) axis was oriented vertically from the distal segment end to the proximal segment end. The Y (coronal) axis was oriented within the segment from posterior to anterior. Finally, the X (sagittal) axis orientation was determined using the right-hand rule and directed from medial to lateral (Figure 1).

2.6. Data processing

Dynamic trials were digitized using Qualisys Track Manager (Qualisys Medical AB, Goteburg, Sweden) to identify anatomical and tracking markers, then exported as C3D files to Visual 3D (C-Motion, Germantown, MD, USA). All data were linearly normalized to 100% of the stance phase. GRF data and marker trajectories were smoothed with cut-off frequencies of 50 Hz at 12 Hz respectively, using a low-pass Butterworth 4th order zero lag filter.

<u>Running biomechanics</u>

In accordance with the methods described by Addison and Lieberman [49], an impulse-momentum modelling technique was utilized to calculate the effective mass (%BW), i.e., the proportion of the bodyweight that comes to a full stop during the impact phase. This parameter was evaluated using the following formula:

Effective mass = Integral of the vertical GRF /
(Δ foot vertical velocity + gravity × Δ time)

The impact peak was delineated in conventional running shoes as the first discernible peak in the vertical GRF. However, in the case of minimal footwear, where a consistent impact peak is not always apparent, we adhered to the criteria set forth by Lieberman et al. [39] and Sinclair et al. [50]. Accordingly, we positioned the impact peak in minimal footwear at the same relative location as observed in conventional running shoes. The time it took to reach the impact peak (referred to as Δ time) was measured as the duration from footstrike to the occurrence of the period impact peak. The integral of the vertical GRF was calculated during the impact peak period using a trapezoidal function. Additionally, the change in foot vertical velocity (Δ foot vertical velocity) was determined as the difference in vertical foot velocity between the moments of footstrike and the impact peak, following the methodology of Chi and Schmitt [51]. Foot velocity was assessed by quantifying the vertical velocity of the foot segment's centre of mass within Visual 3D [50].

Loading rate (BW/s) was also extracted by obtaining the peak increase in vertical GRF between adjacent data points using the first derivative function within Visual 3D [43]. The strike index, which serves as an indicator of the foot strike pattern, was calculated by considering the position of the centre of pressure at footstrike in relation to the entire length of the foot. This calculation followed the procedures delineated by Squadrone et al. [19]. A strike index (%) falling within the range of 0–34% indicated a rearfoot strike pattern, >34–67% signified a midfoot strike pattern, and >67–100% represented a forefoot strike pattern. Furthermore, the step length (m) was determined as the horizontal position of the foot's centre of mass between the right and left limbs at footstrike, in accordance with the methodology provided by Sinclair et al. [52]. Running velocity (m/s) was also quantified within Visual 3D, using the linear velocity of the model centre of mass in the anterior direction [52].

Musculoskeletal simulation

Data associated with the stance phase were exported from Visual 3D to OpenSim 3.3 software (Simtk.org, Stanford, CA). To cater to the unique anthropometric characteristics of each participant, a validated musculoskeletal model was used, which underwent scaling to accommodate the individual anthropometric characteristics of each participant. It featured 12 segments, 19 degrees of freedom, and a total of 92 musculotendon actuators [53]. This model was employed to estimate muscle and joint contact forces in the lower extremities. Initially, a residual reduction algorithm, as detailed by Delp et al. [54], was applied to address any dynamic inconsistencies between the kinematics derived from the measured GRF and the model. Subsequently, muscle kinetics were determined through static optimization procedures, following the methods described by Steele et al. [55].

As muscle forces represent the primary factor influencing joint contact forces [56], subsequent to the static optimization procedure, three-dimensional ankle joint contact forces, presented in the tibial reference frame, were computed through the joint reaction analysis function within OpenSim. This process utilized the muscle forces derived from the static optimization procedure as input. The resulting ankle joint contact force was determined using three-dimensional Pythagorean theorem, and normalized ankle joint contact forces (BW) were extracted for each anatomical axis (anterior-posterior, axial, and medio-lateral) at the moment of the peak resultant load.

From the aforementioned static optimization procedures, the normalized muscle forces (BW) with tibial attachment (including biceps femoris long head, biceps femoris short head, extensor digitorum longus, extensor hallucis longus, flexor digitorum longus, flexor hallucis longus, gracilis, rectus femoris, sartorius, semimembranosus, semitendinosus, soleus, tensor fasciae latae, tibialis anterior, tibialis posterior, vastus intermedius, vastus lateralis, and vastus medialis) were extracted at the moment of the peak resultant ankle joint contact force. Furthermore, muscle forces from other muscles crossing the ankle joint, namely medial gastrocnemius, lateral gastrocnemius, peroneus brevis, peroneus longus, and peroneus tertius, were also obtained at the same relative time point.

Finally, the attachment points of each of the aforementioned muscles (with tibial attachment) were extracted using the OpenSim plugin developed by van Arkel et al. [57] (https://simtk.org/projects/force_direction). Using the same plug-in, anatomically directed muscle forces onto the tibia at their attachment points, for each muscle were calculated at the instance of the peak resultant ankle joint contact force in all three anatomical directions. Positive values represent anterior, upwards and laterally directed forces onto the tibia.

Finite element analyses

FEBio software (developed by Musculoskeletal Research Laboratories, Salt Lake City, Utah) was utilized to conduct the finite element analysis necessary for calculating tibial strains. The construction of the tibial surface and trabecular model involved employing the statistical shape modelling source code developed by Keast et al. [58] (accessible at https://simtk.org/projects/ssm_tibia). The resulting model comprised 33,004 quadratic tetrahedral elements (Figure 2). Material properties were designated based on those previously adopted by Edwards et al. [37], with an elastic modulus of 17.0 GPa for cortical bone and 1.0 GPa for trabecular bone. Both components were attributed a Poisson's ratio of 0.3 [37].

Each model had boundary conditions imposed, involving complete constraints applied at the tibial plateau [59, 60] (Figure 2a). Net three-dimensional ankle joint contact forces, derived from the musculoskeletal simulation analyses, were then applied to the distal aspect of the tibia [59, 60] (Figure 2b). Additionally, anatomically directed net muscle forces were applied at every muscle attachment point on the tibia, utilizing the forces obtained from static optimization (Figure 2c). Given that certain bi-articulating muscles, such as the gastrocnemius, generate substantial forces during running without direct insertion points onto the tibia itself [59, 60], their contribution to tibial strain was accounted for by calculating a residual ankle joint moment following the approach outlined by Haider et al. [59]. This residual moment was applied to the distal tibia (Figure 2d). The 90th percentile von Mises strain ($\mu\varepsilon$) was then extracted for subsequent analysis [61].

Figure 2. Depiction of finite element model mesh with loading and boundary conditions. The tibial plateau was fully constrained (a.). Ankle joint contact forces were applied to the distal tibia (b.), muscle forces (not all shown here) were applied as concentrated forces at their insertion point onto the tibia (c.) and residual moments were applied at the distal tibia (d.).

Probabilistic stress fracture model

We determined the probability of stress fracture for each participant in each footwear condition firstly by accounting for the daily running distance which was included into the model as runners completed 5.0 km/day for 100 consecutive days [30, 37, 60, 62]. The number of loading cycles/footfalls per day in each footwear condition was quantified by dividing the modelled daily running distance i.e. 5.0 km by the stride length in each footwear outlined above [62].

The probability of tibial stress fracture was assessed through a probabilistic model considering bone damage, repair, and adaptation, aligning with methodologies from prior analyses [30, 37, 60, 62]. The fatigue life of the tibial bone was modelled based on the standard fatigue equation [63]:

$$\mathbf{FLT = C\Delta\varepsilon^{-n}}$$

In the above equation, FLT represents the number of loading cycles to failure and $\Delta\varepsilon$ denotes the strain range obtained from finite element analysis. Since strain magnitude is zero for certain modelled tibial elements, the maximum strain magnitude from the finite element analysis was utilized to denote the strain $\Delta\varepsilon$. The variable 'n' signifies the slope of the stressed-life curve of bone, and 'C' is a constant. Carter & Caler [63] found a slope of n = 6.6 for fatigue damage of bone at strain magnitudes corresponding to human locomotion [30, 37, 60, 62].

As bone adaptation is mediated as a function of applied loading, there is a con-current increase in bone cross-sectional area, leading to a gradual attenuation of tibial strains over time. Considering a maximum deposition of lamellar bone accumulation at 4 μm/day on the periosteum membrane [64], an adaptation function was quantified using beam theory-based equations [30, 37, 60, 62]. This adaptation function was calculated as the ratio of strain following bone accumulation to strain with the initially modelled bone geometry. The product of this adaptation function and $\Delta\varepsilon$ was employed to determine alterations in tibial strains due to bone adaptation. An equivalent strain ($\Delta\varepsilon$AD) for each element, accounting for adaptation, was then computed, where tT represents the total modelled duration over which bone adaptation occurred (i.e., 100 days) [65]:

$$\mathbf{\Delta\varepsilon_{AD} = (1/tT \int^{Tt}_0 \Delta\varepsilon^n dt)^{1/n}}$$

Given the significant variation in the fatigue life of bone, a widely employed technique in fatigue mechanics to assess the probability of bone failure with adaptation (PfA) is the Weibull approach [66]. Hence, a modified Weibull function was employed, taking into account stressed volume [66]:

$$\boldsymbol{Pf_A} \mathbf{= 1 - exp\ [- (V_s/ V_{so})\ (t/t_f)^{w}]}$$

The variables for the above equation were derived from literature on experimental fatigue testing. This enables the calculation of PfA for a specimen with the stressed volume Vs (obtained from finite element meshes) over the time interval from zero to t. Here, Vso represents the reference stressed volume, tf is the reference time until failure at the applied strain range and number of loading cycles per day, and w signifies the degree of scatter in the material.

As $\Delta\varepsilon$AD varies across the entire tibial body, PfA exhibits differences from one element to another. Through the finite element analysis, unique PfA indices could be determined for each element. If there are k total elements, the PfA for the entire tibial body represents the probability of failure for any single element [67]:

$$\boldsymbol{Pf_A} \mathbf{= 1 - (1 - P_1)(1 - P_2)(1 - P_3)\ldots(1 - P_k).}$$

Elements with comparable strain magnitudes were clustered together, following the approach of Taylor & Kuiper [67], who established that eight element groups could be employed without substantial error. The stressed volume (Vs) for each of the eight groups was computed by adding up the element volumes within each group. Subsequently, using the strain values from each group, the aforementioned formulae were applied to calculate a singular PfA for the entirety of the tibia.

Similarly to the variability observed in the fatigue life of bone, there is significant diversity in the duration required for the repair of bone microcracks. As estimated by Taylor et al. [65], this repair time is approximately 18.5 ± 12.5 days. Consequently, the cumulative probability of bone repair (PR) was determined by employing a second Weibull function [65]:

$$\boldsymbol{P_R = 1 - \exp [- (t/t_r)^m]}$$

where t_r is the reference time for repair and m articulates the degree of scatter in repair time.

Lastly, by calculating the probability that bone will not undergo repair (1-PR) and multiplying it by the instantaneous probability of PfA, integration over time resulted in the cumulative probability of tibial bone failure expressed as a percentage (%) with repair and adaptation (PfRA).

2.7. Statistical analyses

Descriptive statistics, including means and standard deviations, were provided for each continuous outcome measure. Furthermore, in order to contrast the magnitude of the changes in primary and secondary outcomes at both 10-weeks, linear mixed effects models were employed, with group modelled as a fixed factor and random intercepts by participants adopted [68]. For linear mixed models, the adjusted mean difference (*b*), t-value, and 95% confidence intervals of the difference are reported. These analyses were conducted on an intention-to-treat basis, employing the restricted maximum-likelihood method [68]. Effect sizes were calculated for the changes from baseline to 10-weeks between the two groups, using Cohen's *d*, in accordance with McGough & Faraone [69]. Cohen's *d* values were interpreted as 0.2 = small, 0.5 = medium, and 0.8 = large [70]. In addition, a two-way Pearson's chi-squared (X^2) test of independence with probability values calculated by Monte Carlo simulation was used to assess differences between control and footstrike groups, in whether the footstrike pattern (classified using the strike index) changed from baseline to 10-weeks. All statistical analyses for significance were performed using SPSS v28 (IBM, SPSS). A significance level of $P \leq 0.05$ was considered for all analyses. For conciseness and clarity, only variables demonstrating statistical significance attributable to the intervention are presented in the Results section.

3. Results

<u>*Loss to Follow-Up and Adverse Events*</u>

There were no adverse events in either group and all runners who were enrolled at baseline completed the study.

<u>*Running biomechanics*</u>

Reductions in effective mass and the loading rate were significantly greater in the footstrike group compared to the control one (Table 2; Figure 3). In addition, increases in the strike index were significantly greater in the footstrike group compared to the control one (Table 2). In the control group none of the 10 runners altered their strike classification, yet in the footstrike group 9 runners changed their strike classification. The chi-squared test was significant ($X^2_{(1)} = 16.36$, $P < 0.001$), indicating that significantly more runners altered their strike classification in the footstrike group.

Table 2. Running biomechanics (mean ± standard deviations).

	Control				Footstrike				*b*	95% CI		P-value	*d*
	Baseline		10-weeks		Baseline		10-weeks						
	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*		Lower	Higher		
Effective mass (%)	11.34	1.71	11.32	2.06	9.34	1.97	7.78	1.93	***-1.54***	***-2.82***	***-0.26***	***0.021***	***-1.13***
Strike index (%)	13.61	3.64	12.41	3.48	21.79	7.40	65.74	21.17	***45.15***	***30.52***	***59.78***	***<.001***	***2.90***
Step length (m)	1.26	0.18	1.25	0.17	1.28	0.02	1.27	0.04	0.00	-0.09	0.10	0.950	0.03
Running velocity (m/s)	4.11	0.89	4.07	0.82	3.67	0.29	3.63	0.35	0.00	-0.21	0.22	0.974	0.02
Loading rate (BW/s)	170.13	48.92	197.87	79.70	165.85	55.65	100.01	13.14	***-93.58***	***-145.98***	***-41.17***	***0.001***	***-1.678***

Bold text = significant difference in the changes from baseline to 10-weeks days between the two groups (negative values denote that reductions in the footstrike group exceeded those in control), *b* = mean difference between groups in change from baseline to 10-weeks, 95% CI = confidence intervals of the mean difference and *d* = Cohen's d

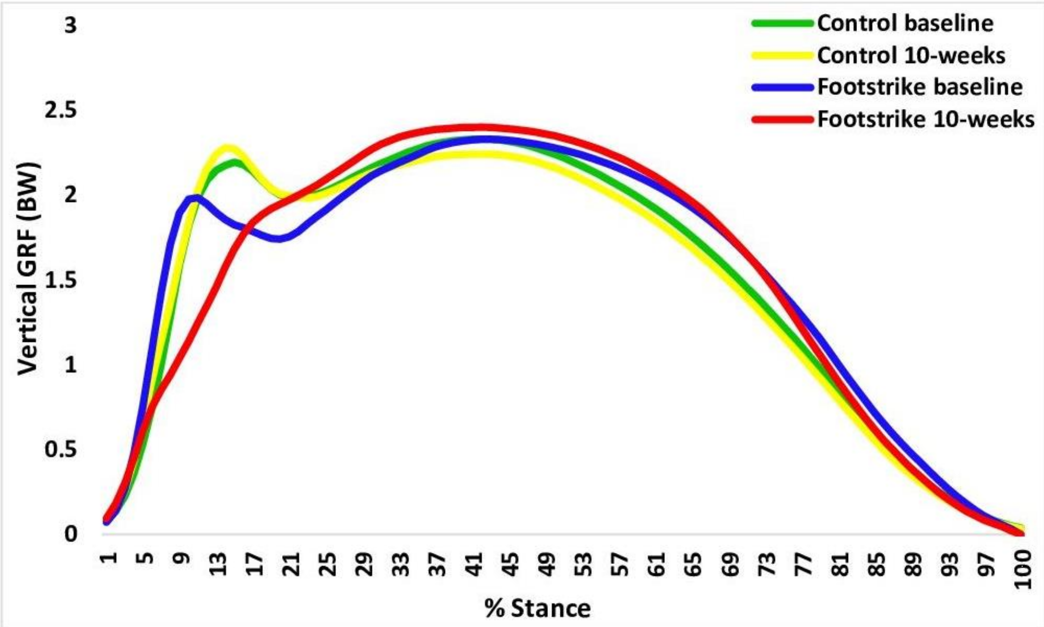

Figure 3. Vertical GRF pre and post transition (a. = tibial acceleration, b. = vertical GRF).

<u>*Musculoskeletal simulation*</u>

Ankle joint contact forces

No statistically significant differences (P > 0.05) in joint contact forces were found (Table 3).

Muscle forces

Increases in semimembranosus, vastus intermedius, vastus lateralis and vastus medialis were *significantly* greater in the footstrike group compared to control (Table 3).

Table 3. Joint contact and muscle forces (mean ± standard deviations)

	Control				Footstrike				*b*	95% CI		P-value	*d*
	Baseline		10-weeks		Baseline		10-weeks						
	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*		Lower	Higher		
Posterior tibial load (BW)	2.55	0.53	2.43	0.41	2.79	0.51	2.77	0.21	0.11	-0.29	0.50	0.582	0.25
Axial tibial load (BW)	9.50	1.84	9.58	1.70	10.32	0.77	11.70	1.91	1.31	-0.43	3.05	0.131	0.71
Medial tibial load (BW)	1.27	0.68	1.17	0.49	0.94	0.36	1.07	0.47	0.23	-0.07	0.54	0.126	0.72
Biceps femoris long head (BW)	0.27	0.27	0.18	0.15	0.21	0.18	0.28	0.16	0.17	-0.01	0.34	0.065	0.88
Biceps femoris short head (BW)	0.02	0.05	0.01	0.02	0.13	0.27	0.14	0.26	0.01	-0.02	0.05	0.342	0.44
Extensor digitorum longus (BW)	0.16	0.17	0.10	0.09	0.12	0.13	0.08	0.11	0.03	-0.07	0.13	0.574	0.26
Extensor hallucis longus (BW)	0.05	0.05	0.02	0.03	0.05	0.04	0.03	0.04	0.00	-0.03	0.04	0.863	0.08
Flexor digitorum longus (BW)	0.02	0.02	0.01	0.02	0.12	0.17	0.15	0.18	0.03	-0.09	0.15	0.559	0.27
Flexor hallucis longus (BW)	0.05	0.06	0.02	0.03	0.12	0.15	0.18	0.20	0.09	-0.04	0.22	0.182	0.62
Gracilis (BW)	0.00	0.00	0.00	0.00	0.00	0.01	0.00	0.01	0.00	-0.01	0.01	0.930	-0.04
Rectus femoris (BW)	1.80	0.33	2.11	0.52	1.79	0.61	1.67	0.71	-0.42	-1.00	0.15	0.139	-0.69
Sartorius (BW)	0.09	0.12	0.06	0.09	0.06	0.09	0.07	0.11	0.04	-0.04	0.11	0.312	0.47
Semimembranosus (BW)	0.40	0.40	0.22	0.21	0.35	0.18	0.47	0.25	***0.30***	***0.03***	***0.57***	***0.031***	***1.05***
Semitendinosus (BW)	0.02	0.05	0.04	0.07	0.11	0.09	0.14	0.11	0.01	-0.04	0.06	0.619	0.23
Soleus (BW)	4.31	1.16	4.55	1.13	4.52	0.84	4.62	0.60	-0.14	-1.09	0.81	0.758	-0.14
Tensor fasciae latae (BW)	0.34	0.25	0.37	0.18	0.48	0.05	0.48	0.04	-0.03	-0.16	0.09	0.589	-0.25
Tibialis anterior (BW)	0.03	0.05	0.02	0.03	0.21	0.30	0.11	0.19	-0.10	-0.21	0.01	0.080	-0.83
Tibialis posterior (BW)	0.93	0.65	1.11	0.64	1.36	0.43	1.55	0.38	0.01	-0.63	0.65	0.972	0.02

	Control				Footstrike				*b*	95% CI		P-value	*d*
	Baseline		10-weeks		Baseline		10-weeks						
	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*		Lower	Higher		
Vastus intermedius (BW)	1.35	0.52	1.34	0.45	1.07	0.34	1.43	0.30	***0.37***	***0.11***	***0.63***	***0.008***	***1.33***
Vastus lateralis (BW)	1.84	0.76	1.86	0.61	1.48	0.46	1.94	0.39	***0.45***	***0.11***	***0.79***	***0.012***	***1.25***
Vastus medialis (BW)	1.28	0.50	1.26	0.43	1.01	0.32	1.35	0.29	***0.37***	***0.11***	***0.63***	***0.009***	***1.32***
Lateral gastrocnemius (BW)	1.03	0.28	0.95	0.19	1.00	0.12	1.00	0.24	0.08	-0.19	0.36	0.535	0.28
Medial gastrocnemius (BW)	2.22	0.34	2.30	0.31	2.07	0.26	2.17	0.39	0.03	-0.39	0.44	0.897	0.06
Peroneus brevis (BW)	0.14	0.16	0.14	0.17	0.18	0.12	0.22	0.13	0.04	-0.12	0.21	0.576	0.26
Peroneus longus (BW)	1.05	0.35	0.97	0.45	1.17	0.48	1.26	0.49	0.17	-0.07	0.41	0.150	0.67
Peroneus tertius (BW)	0.04	0.06	0.01	0.01	0.05	0.05	0.02	0.03	0.01	-0.04	0.06	0.751	0.14

Bold text = significant difference in the changes from baseline to 10-weeks days between the two groups (negative values denote that reductions in the footstrike group exceeded those in control), *b* = mean difference between groups in change from baseline to 10-weeks, 95% CI = confidence intervals of the mean difference and *d* = Cohen's d

Finite element analysis

No statistically significant differences (P > 0.05) in tibial strains were found (Table 4; Figure 4).

Table 4. Finite element analysis outcomes (mean ± standard deviations).

	Control				Footstrike				*b*	95% CI		P-value	*d*
	Baseline		10-weeks		Baseline		10-weeks						
	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*		Lower	Higher		
90th percentile Von Mises strain (με)	4273.29	996.53	4079.80	859.27	3679.07	601.00	3787.48	464.07	301.90	-106.35	710.16	0.138	0.70

b = mean difference between groups in change from baseline to 10-weeks, 95% CI = confidence intervals of the mean difference and *d* = Cohen's d

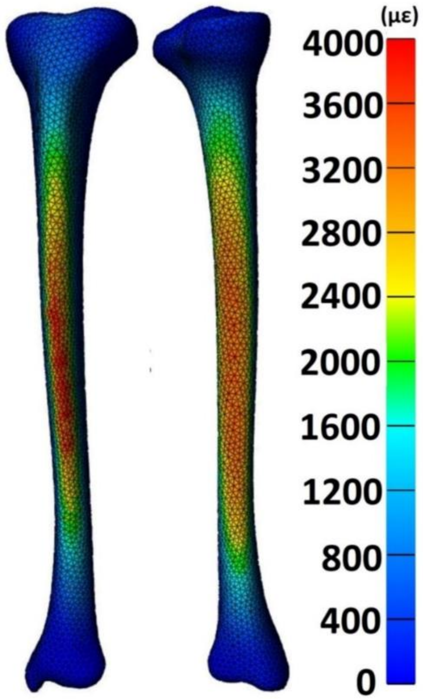

Figure 4. Representative tibial strain distribution on the tibia.

Stress fracture probability

No statistically significant difference (P > 0.05) in stress fracture probability was found (Table 5; Figure 5).

Table 5. Probabilities of failure (mean ± standard deviations).

	Control				Footstrike				*b*	95% CI		P-value	*d*
	Baseline		10-weeks		Baseline		10-weeks						
	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*		Lower	Higher		
Failure probability (%)	15.43	11.83	13.39	12.21	12.82	13.97	10.82	10.77	0.04	-7.23	7.31	0.991	0.01

b = mean difference between groups in change from baseline to 10-weeks, 95% CI = confidence intervals of the mean difference and *d* = Cohen's d

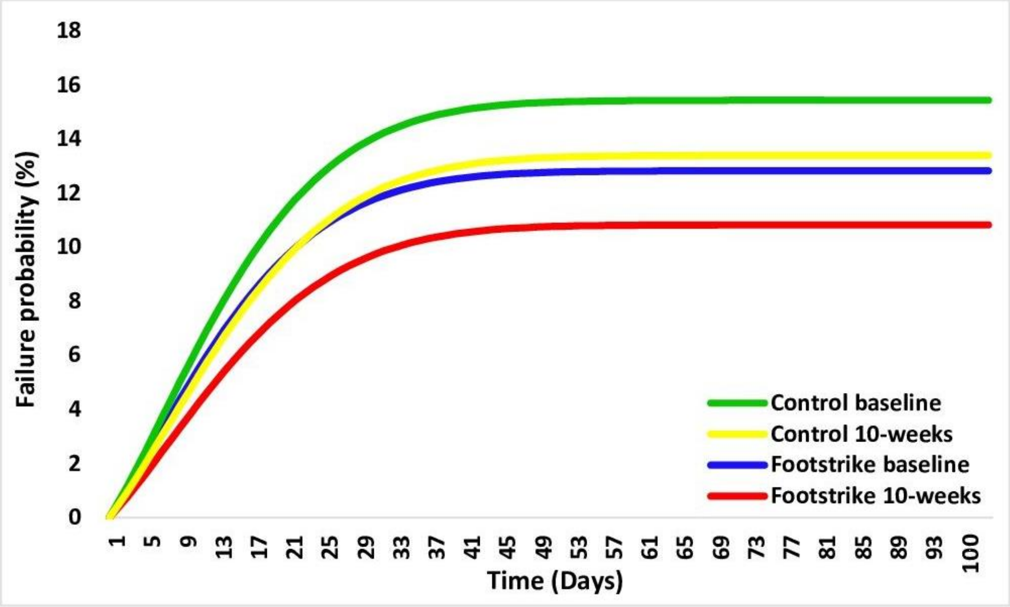

Figure 5. Average probabilities of failure (PFRA) in each group across 100 days of running.

4. Discussion

The primary aim of the current study was to investigate the effects of a 10-week footstrike transition program on tibial stress fracture probability compared to a control group. To date, this represents the first investigation to explore the effects of a footstrike transition intervention using a randomized controlled trial on tibial stress fracture probability in runners. The primary objective was to assess the impact of footstrike transition on tibial stress fracture probability, whilst the secondary goals were to investigate running biomechanics, muscle forces, joint contact forces, and tibial strains.

Regarding the primary outcome, the results from the present study do not align with our hypothesis, as there were no significant reductions in tibial stress fracture probability in the footstrike group compared to the control one. This observation concurs with the acute non-randomized observations of Chen et al. [30], who also showed no differences in stress fracture probability with a modified footstrike pattern. Stress fractures are representative of a mechanical fatigue phenomenon, whereby bone strains initiate microscopic damage in the bony matrix [16]. Therefore, as the analysis of secondary study outcomes revealed no differences in tibial strains or stride length characteristics that would alter the number of daily loading cycles between control and footstrike groups, it is to be expected that stress fracture probability was not significantly altered. This investigation importantly indicates that altering the footstrike does not appear to influence tibial stress fracture probability, and thus at the current time this approach cannot be advocated for runners seeking to reduce their risk from tibial stress fractures.

However, this trial did notably show that the foot contact location was moved significantly more anteriorly in the footstrike group in relation to the control group. When contextualized via the strike index, the chi-squared analyses as well as observation of the vertical GRF curve (showing that the impact which was evident at baseline is no longer present at 10-weeks) support this, as a rearfoot strike was maintained in the control group, whereas a midfoot pattern was revealed in the footstrike group following the 10-week intervention period. This importantly shows that footstrike can be successfully modified using the intervention that was described within this trial. This protocol may therefore be used in future studies seeking to allow habitual rearfoot strike runners to successfully modify their foot contact pattern.

A further important finding from the current study is that reductions in the loading rate were significantly greater in the footstrike group compared to control. It is proposed that this finding relates to the corresponding statistical reductions in effective mass that were also revealed in the footstrike group. This observation was expected considering the aforementioned alterations in foot contact position and also the observations of Sinclair et al. [50] demonstrating significant positive associations between effective mass and the loading rate. Transient loading is governed by the rate at which the momentum of the foot changes, so consideration of the impulse-momentum model indicates that when a rearfoot strike pattern is adopted, the majority of the vertical momentum is absorbed by the collision as a greater proportion of body mass is decelerated during the impact phase [39]. When a runner exhibits a non-rearfoot contact position, the vertical momentum is converted into rotational momentum, thus the total mass being decelerated is reduced, leading to a reduction in the magnitude of impact loading experienced by the body [49, 50]. Reductions in the loading rate in the footstrike group may have clinical relevance as although tibial stress fracture risk was not significantly reduced and the vertical rate of loading has been shown to be unrepresentative of tibial loading [21], it has been linked to the aetiology of plantar fasciitis [71] and to prospectively differentiate between injured runners from those who had never been injured [72]. As such, although further investigation is certainly required, subsequent intervention trials could consider the efficacy of footstrike modification on other musculoskeletal injuries in runners, beyond those investigated in the current study.

Overall, the current study demonstrated a high retention rate in the intervention group, without evidence of any adverse effects. This suggests that footstrike modification interventions appear to be safe and tolerable modalities in runners. Although, this trial demonstrated no significant effects of the footstrike intervention on the primary outcome as well as secondary indices in relation to tibial strains, the trial does notably show that footstrike can be successfully modified using the intervention that was implemented. A cost-effectiveness analysis was beyond the scope of this investigation; however, it appears that footstrike can be successfully modified over a 10-week period at a relatively low cost. Therefore, whilst the footstrike intervention that was adopted within this trial was not successful in reducing the risk and indeed risk factors for tibial stress fractures, future randomized interventions may be able to utilize the footstrike modification intervention adopted in the current study to modify the risk for other musculoskeletal pathologies in runners.

As with all experimental research, this trial is not without limitations. Firstly, the fact that compliance to the footstrike intervention programme and exercises was not quantified may serve as a potential drawback. Furthermore, running training volume across both trial arms was not measured, so it may also represent a limitation to the current investigation. Although the foot contact position was significantly influenced in the footstrike group, increased or indeed reduced compliance and the extent of total running volume could have influenced the magnitude of the responses to the intervention. In relation to the fracture probabilities, it is important to acknowledge that our values [37, 62] and the acceleration of risk over the first 40-days [73] is consistent with the epidemiological literature for runners experiencing tibial stress fractures. However, as our finite element model was scaled to individual participant dimensions, person-specific bone geomorphologies and material properties were not considered. As both geometry and density can influence the magnitude of the experienced bone strains [74, 75], the model utilized within this study may not have quantified tibial strains with complete accuracy. Therefore, despite the inherent challenges, future analyses should seek to utilize participant specific finite element properties as inputs into the probabilistic tibial stress fracture model.

5. Conclusions

The current study aimed to investigate, using a randomized controlled trial, the effects of a 10-week footstrike transition program compared to control, using a collective finite element analysis and computational probabilistic modelling-based approach. This trial notably showed no significant improvements in tibial stress fracture probability in the footstrike group compared to the control one, suggesting that the footstrike intervention adopted in the current investigation is not effective in mediating improvements tibial stress fracture risk. However, this study did, importantly, show that footstrike could be successfully modified using the intervention that was implemented, as well as it could mediate significant reductions in both effective mass and the loading rate. Therefore, since the loading rate has been proposed as being linked to the aetiology of a range of chronic running injuries, future intervention trials should consider examining the efficacy of footstrike modification on other musculoskeletal injuries in runners, beyond those investigated in the current study.

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