[RESEARCH REPORT]

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Motion-Control Shoes Reduce the Risk of Pronation-Related Pathologies in Recreational Runners: A Secondary Analysis of a Randomized Controlled Trial

Prospective studies that aim to identify sports injury risk factors typically include a broad range of acute and chronic injuries to different anatomical locations. In most studies, the role of risk factors in the underlying mechanism is not obvious and differs across injury types. When investigating foot type as a risk factor for lower-limb injuries, a pronated foot might be a risk factor for medial tibial stress syndrome,[18] but a supinated foot might be a risk factor for ankle sprain.[12] When the effect of foot type is investigated on both injury types concurrently, the effect might be masked, because it tends to be averaged out. Research aiming to identify risk factors for injury should distinguish between injuries that are related to that risk factor and injuries that are not.

OBJECTIVE: To investigate whether motion-control shoes reduce the risk of pronation-related injuries in recreational runners.

DESIGN: Secondary analysis of a randomized controlled trial of the effect of shoes on running injuries.

METHODS: Three hundred seventy-two recreational runners were randomized to receive either standard neutral or motion-control shoes and were followed up for 6 months regarding running activity and injury. Running injuries that occurred during this period were registered and classified as pronation-related injuries (Achilles tendinopathy, plantar fasciopathy, exercise-related lower-leg pain, and anterior knee pain) or other running-related injuries. With the use of competing risk analysis, the relationship between pronation-related and other running-related injuries and shoe type was evaluated by estimating the cause-specific hazard, controlling for other possible confounders like age, sex, body mass index, previous injury, and sport participation pattern.

RESULTS: Twenty-five runners sustained pronation-related running injuries and 68 runners sustained other running-related injuries. Runners wearing the motion-control shoes had a lower risk of pronation-related running injuries compared with runners who wore standard neutral shoes (hazard ratio = 0.41; 95% confidence interval: 0.17, 0.98). There was no effect of shoe type (hazard ratio = 0.68; 95% confidence interval: 0.41, 1.10) on the risk of other running-related injuries.

CONCLUSION: Motion-control shoes may reduce the risk of pronation-related running injuries, but did not influence the risk of other running-related injuries. *J Orthop Sports Phys Ther 2021;51(3):135-143. Epub 11 Dec 2020. doi:10.2519/jospt.2021.9710*

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Runners frequently sustain injuries.[31] Increased and poorly timed foot pronation during the running gait cycle and movements that contribute to foot pronation (eversion, abduction, and dorsiflexion) have frequently been cited as risk factors for exercise-related lower-leg pain, medial tibial stress syndrome, stress fractures of the tibia, Achilles tendinopathy, plantar fasciopathy, patellar tendinopathy, and anterior knee pain.[1,13,17,26,32,33] Alterations in the movements at the foot-ankle complex resulting in abnormal repetitive load can cause injuries at the foot-ankle complex, and more proximally in the kinetic chain.[6]

Motion-control footwear may be effective in reducing (1) the amount of foot pronation during running[3] and (2) running-injury risk among regularly active recreational runners.[15] However, we suggest that it is more accurate to investigate the effect of motion-control shoes on the development of injuries specifically related to foot pronation, given that this shoe

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technology focuses, at least theoretically, on limiting excessive pronation.

We aimed to investigate the effect of motion-control shoes on the development of pronation-related running injuries, which were defined based on existing evidence and/or a theoretically plausible mechanism (**TABLE 1**). We hypothesized that motion-control shoes with a medial foot support aimed at reducing excessive pronation would reduce the risk of pronation-related running injuries in recreational runners compared to shoes with no motion-control technology. Our secondary aim was to assess whether wearing motion-control shoes influenced the development of other running-related injuries (RRIs).

METHODS

Data from a previously published randomized controlled trial[15] were reanalyzed. To be included, participants had to be healthy, to be aged 18 to 65 years, to practice regular running (at least 1 session per week) for at least 6 months over the 12 months prior to the study, and to have no contraindication to perform running activity, no prior (in the last 12 months) surgery to the lower limbs or low back, and no use of orthopaedic insoles for running activities. All volunteers were required to perform at least 1 running activity per week during the 6-month follow-up period. At least once per week throughout the follow-up period, participants had to report all sports activities and injuries or pain experienced during the follow-up. Information about the participants, including age, sex, running regularity over the previous 12 months (months of practice), running experience (years of regular practice), and previous injury to the lower limbs or low back preventing normal running activity during the preceding 12 months, was collected by questionnaire.

The baseline evaluation included assessment of foot posture using the 6-item

TABLE 1 PRONATION-RELATED RUNNING INJURIES: LOCATION OF COMPLAINTS AND THEORETICAL OR EVIDENCE-BASED MECHANISMS LINKING THE ASPECTS OF PRONATION TO THE INJURY

Pronation-Related Running Injury	Location and Complaints	Aspect of Pronation Linked to the Injury (Evidence Based)	Pathophysiological Mechanisms (Theoretical)
Achilles tendinopathy	Pain at the Achilles tendon during stretching or during contraction of the plantar flexors of the foot	Increased rearfoot eversion at heel strike in shod running (strong evidence) and ankle eversion range of motion in the barefoot condition (conflicting evidence) were shown in runners with Achilles tendinopathy compared to controls[17]	Excessive pronation causes a vascular constriction of the Achilles tendon, described as the "whipping phenomenon"[4]
Plantar fasciopathy/heel pain	Pain at the origin of the plantar fascia at the calcaneal insertion point	Increased forefoot pronation, determined when the clinician observed excessive pronation during gait compared with standing, increased the risk of presenting with plantar fasciopathy[32] Maximum rearfoot eversion, together with arch-height motion, was shown to be a good predictor of plantar fascia tension[13]	Excessive pronation could indirectly cause additional stress on the plantar fascia, leading to plantar fasciopathy[13,32]
Exercise-related lower-leg pain	Pain at the middle to lower third of the lower leg that occurs with exercise	Increased barefoot peak rearfoot eversion was shown in runners with exercise-related lower-leg pain compared with healthy runners[17] Increased 3-D pronation excursion, accompanied by more pressure underneath the medial side of the foot and delayed maximal eversion, increased the risk for developing exercise-related lower-leg pain[33]	The foot and the knee are mechanically linked by the tibia, and because of the inclined axis of the subtalar joint in the sagittal plane, pronation of the foot leads to internal rotation of the tibia.[7,8,25] Some authors suggest that inflammation of the periosteum is due to excessive traction (traction theory) caused by excessive and/or prolonged pronation.[2] Others support the view that exercise-related lower-leg pain is not an inflammatory process of the periosteum, but rather a bone stress reaction (bone stress theory)[19]
Anterior knee pain/patellar tendinopathy	Pain in the anterior and central aspects of the knee	Increased peak ankle eversion during running was shown in female runners with patellar tendinopathy compared to controls[17] An increased coupling vector between eversion and tibial internal rotation, toward tibial internal rotation, was shown in runners with anterior knee pain[26]	Excessive and/or prolonged pronation is thought to keep the tibia internally rotated as the knee begins to extend, thus disrupting the "screw home mechanism." To preserve this screw home mechanism, the femur is believed to compensate by internally rotating more than the tibia and therefore achieving the knee external rotation needed for the knee to extend. However, while this compensation at the femur is thought to preserve the kinematics at the tibiofemoral joint, it disrupts those of the patellofemoral joint, placing increased stress on its articular cartilage and surrounding soft tissue, possibly leading to anterior knee pain or patellar tendinopathy[26]

Foot Posture Index.[24] Because the unit of analysis was the participant, classification into 1 of the 5 categories was based on the foot with the most extreme score. The period between baseline evaluation and the beginning of follow-up lasted 3 months. Participants who reported an injury during this period were excluded. All participants received a full description of the study protocol and provided written informed consent for participation. The Luxembourg National Ethics Committee for Research (201211/04) approved all procedures.

After recruitment and baseline assessment, all runners were randomized to wear the "standard shoe" or the "motion-control shoe" during all running activities. We stratified by age (2 strata, based on the median), body mass index (2 strata, based on the median), and foot morphology (highly pronated, pronated, neutral, supinated, and highly supinated, based on the Foot Posture Index). A renowned sport equipment manufacturer provided the 2 versions of the shoe model, which were de-identified so that the study participants and the researchers did not know which type of shoe they were given. Motion-control shoes had (1) a thermoplastic polyurethane structure located at the medial part of the midfoot, and (2) a dual-density, ethylene vinyl acetate midsole located at the forefoot, and the standard shoe did not have these features. A detailed description and a depiction of the shoes can be found in the original article.[15]

During the follow-up, data related to the training sessions and injuries of the participants were collected via a dedicated internet-based platform (www.tipps.lu). The type of activity, context, duration, subjectively perceived intensity measured using the Borg 0-to-10 category ratio scale, distance covered, running surface, and shoes worn were registered for each session. Participants also reported any pain or injury sustained during the session. The response to each item was mandatory for every declared training session or competition and could be selected from a predefined list. In case of injury, the anatomical location was reported on a graphical interface within the internet-based platform, using standardized injury characteristics from a predefined list (see the **APPENDIX**).[9,16] The research team checked the coherence and completeness of self-reported data for every injury by phone and invited participants to return to the laboratory for a final visit to check all injury data at the end of the study.

Injury Definition

An injury was defined as any pain in the lower limbs or low back region, sustained during or as a result of running, impeding planned running activity for at least 1 day (time-loss definition). The online injury questionnaire has previously been described.[16] Injuries were classified according to consensus guidelines on sports injury surveillance studies.[9] As the event of interest in this study was a pronation-related running injury, the RRIs in the original study were reclassified into 2 new categories: (1) pronation-related running injuries, defined as overuse injuries with symptoms of Achilles tendinopathy, exercise-related lower-leg pain, plantar fasciopathy, or anterior knee pain (**TABLE 1**); and (2) other RRIs for which there is no evidence for a pronation-related mechanism (eg, ankle sprains, hamstring strains, iliotibial band syndrome).

Data Analysis

Date at inclusion (shoe distribution date) and date at first injury or at censoring were used to calculate the time at risk. Participants who did not complete their entire running calendar with weekly information were contacted by the research team to ascertain the reason for dropout and to ensure that injury was not the reason for noncompliance. A participant was right censored (1) when no data were uploaded for more than 2 weeks despite an automatic e-mail reminder and a phone call from the research team, (2) in the case of severe disease, (3) for an injury not related to running, (4) for a modification of the running plan not caused by an injury, or (5) at the end of follow-up (shoe return date), whichever came first. Time at risk was expressed in hours spent running and was used as the time scale.

Because we were interested in one type of injury, and one type of injury can hinder the occurrence of another type, appropriate statistical survival analysis with competing risk was used. The effect of shoe type and other potential risk factors on injury risk was investigated by estimating the cause-specific hazard. First, the unadjusted univariable cause-specific hazards were estimated on the occurrence of pronation-related running injuries and other RRIs to present the crude estimates of hazard ratios (HRs).[5] A multivariable model was then built for the cause-specific hazards of pronation-related running injuries and other RRIs, taking into account competing risks. Additionally, the effects of confounding and interaction terms were checked. The recommendation of using at least 10 injuries per predictor variable included in the Cox regression analysis was strictly followed,[23] and the choice of the variables included in the final model was based on the strength of the association observed in the unadjusted models. The threshold for significance was set at .05.

The assumptions of proportionality and linearity of the hazards were investigated by means of log-minus-log plots against time and the Schoenfeld residual global test.[11] The Cox proportional hazard model's goodness of fit was checked using residuals, and time-varying effects were tested by the resampling method.[14,29] All analyses were performed in R Version 3.4.3 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Data from 372 runners (mean age, 40 years; 40% women) who completed the trial were analyzed. Descriptive statistics are presented in **TABLE 2**. As there were few participants with highly pronated and highly supinated feet, these categories were merged with those of pronated and supinated feet, respectively.

Twenty-five (7%) runners sustained pronation-related running injuries: 6 were classified as anterior knee pain, 7 as exercise-related lower-leg pain, 2 as plantar fasciopathy, and 10 as Achilles tendinopathy. Sixty-eight runners (18%) sustained other RRIs: 15 were classified as ankle sprain/instability, 13 as calf muscle cramp/spasm/tear, 12 as thigh muscle cramp/spasm, 5 as foot muscle cramp/spasm, 3 as low back pain, 3 as knee arthrosis/meniscal lesion, 1 as tendinopathy of the hip adductors, 1 as inflammation of the toe joint, and 1 as a contact trauma. In 14 cases (4%), the diagnosis of the event was not clear. Two hundred seventy-nine runners (75%) did not sustain injuries during follow-up and were right censored. Descriptive statistics of the events according to shoe type can be found in **TABLE 3**.

In the **FIGURE**, the effect of shoe type on the occurrence of pronation-related running injuries and other RRIs is shown (ignoring other covariates). The probability of sustaining a pronation-related running injury with the motion-control shoe is lower compared to that of the standard shoe.

Shoe type was a significant predictor of pronation-related running injuries, but not of other RRIs (**TABLE 4**) (estimated univariable, unadjusted cause-specific HRs and their 95% confidence intervals). A previous injury significantly increased the risk for both pronation-related running injuries and other RRIs. A higher body mass index and a lower mean session distance were associated with a higher injury risk for other RRIs.

TABLE 5 presents the multivariable model for pronation-related running injuries, with a significant effect of shoe type and previous injury. Interaction terms between shoe type and previous injury were not significant. The adjusted model for other RRIs showed a significant effect of previous injury and mean session distance (**TABLE 5**).

Proportionality and linearity assumptions for the different covariates for the cause-specific hazards were met, although the coefficient for injury history showed a slight decreasing pattern (ie, a higher effect in the beginning of the study that waned toward the end of the study) (**APPENDIX**). Judging by the global *P* value and the

TABLE 2 Descriptive Statistics of the Study Participants[a]

	All Participants (n = 372)	Standard Neutral Shoe (n = 185)	Motion-Control Shoe (n = 187)
Age, y	40.4 ± 10.5; 40 (19-68)	41.0 ± 11.2	39.9 ± 9.7
Weight, kg	72.3 ± 13.1; 72 (43-114)	72.9 ± 13.1	71.6 ± 13.1
Height, cm	174.4 ± 9.1; 175 (150-198)	174.9 ± 9.1	173.9 ± 9.1
Body mass index, kg/m^2	23.6 ± 3.0; 23.4 (17-36)	23.7 ± 3.0	23.6 ± 3.1
Running experience, y	8.9 ± 9.2; 6 (0-45)	10.0 ± 10.1	7.7 ± 8.0
Weekly distance, km	17.5 ± 13.5; 14.3 (2-133)	17.9 ± 12.0	17.1 ± 14.9
Session duration, min	56 ± 21; 54 (15-333)	56 ± 15	56 ± 26
Session distance, km	8.9 ± 3.1; 8.8 (2.2-35)	9.0 ± 2.6	8.7 ± 3.4
Session intensity, AU (1-10)	3.7 ± 1.0; 3.6 (1.3-7.2)	3.8 ± 1.0	3.7 ± 1.0
Running sessions per week, n	1.9 ± 1.1; 1.6 (0.5-14)	1.9 ± 0.9	1.9 ± 1.3
Other sports sessions per week, n	1.0 ± 1.4; 0.5 (0-8)	1.0 ± 1.5	0.9 ± 1.3
Sex, n (%)			
Male	224 (60.2)	113 (61.0)	111 (59.4)
Female	148 (39.8)	72 (39.0)	76 (40.6)
Previous injury, n (%)			
No	280 (75.3)	48 (25.9)	44 (23.5)
Yes	92 (24.7)	137 (74.1)	143 (76.5)
Foot type, n (%)[b]			
Highly supinated	10 (2.7)	5 (2.7)	5 (2.7)
Supinated	50 (13.4)	25 (13.5)	25 (13.4)
Neutral	218 (58.6)	108 (58.4)	110 (58.8)
Pronated	80 (21.5)	39 (21.1)	41 (21.9)
Highly pronated	14 (3.8)	8 (4.3)	6 (3.2)

Abbreviation: AU, arbitrary unit.
[a]*Values are mean ± SD or mean ± SD; median (range) unless otherwise indicated.*
[b]*Foot-type classification was based on the Foot Posture Index. For participants younger than 60 years of age: highly supinated, –4 or less; supinated, –3 to 0; neutral, 1 to 6; pronated, 7 to 9; highly pronated, 10 or greater. For participants 60 years of age or older: highly supinated, –4 or less; supinated, –3 to 0; neutral, 1 to 7; pronated, 8 to 10; highly pronated, 11 or greater.*[21]

resampling method test, it was suggested that the model fitted the data. Results of goodness-of-fit tests also showed that the model was reasonable (*P* = .333 for model diagnostics [overall proportionality]).

DISCUSSION

Motion-Control Shoes Decrease Pronation-Related Running Injury Risk

Our trial[15] was originally designed to test the effect of shoe type on all kinds of running injuries. In this analysis, we hypothesized that motion-control shoes would have a greater influence on the occurrence of pronation-related running injuries because those shoes are specifically designed to limit excessive pronation. Running with motion-control shoes diminished the hazard for a pronation-related running injury, confirming our main hypothesis. The HR to develop pronation-related running injuries was almost 2.5 times lower with motion-control shoes versus standard shoes. Estimating the effect of motion-control shoes on other RRIs in this study resulted in a nonsignificant HR. In the original trial, the HR of motion-control shoes versus standard shoes for all RRIs was 0.55 (95% confidence interval: 0.36, 0.85; *P* = .005).[15] Comparing the results from the 2 analyses illustrates that the protective effect of motion-control shoes was much greater on pronation-related running injuries, and that the significant effect disappeared for other RRIs. Different results between the original trial and our secondary analysis stress the importance of investigating the effect of an intervention by taking into account the most plausible underlying mechanism, and therefore focusing on the most relevant outcome. Otherwise, there is a possibility that the effect of an intervention might be overlooked and the intervention considered ineffective. We suggest that clinicians consider recommending motion-control shoes to specifically target pronation-related running injuries, as those shoes benefited the recreational runners in our trial.

Injury History Increases Pronation-Related Running Injury Risk

History of injury increased the hazard for pronation-related running injuries and other RRIs. This finding is in agreement with previous studies.[10] The increased effect was higher in the beginning of the study, and the effect vanished with time (**APPENDIX**). Sufficient recovery time is important, while prevention of the first injury may be even more valuable.

Analysis Strategy

Time-to-event models are frequently used in other research settings, but less frequently in sports injury research.[20] Additionally, in some of those sports injury risk factor studies, several different types of injuries occurred during follow-up, while often only 1 injury type was of interest. Injuries that were not of interest were frequently removed from the analysis, which might have resulted in biased estimates. Nielsen et al[22] stressed the importance of competing risk analysis in situations when an individual can experience more than one type of event and when the occurrence of one type of event hinders or influences the occurrence of other types of events. We considered pronation-related running injuries as the event of interest and RRIs from other causes as competing risks.

We measured 13 possible risk factors. Estimating the effect of each risk factor separately is relatively easy. There is no widely agreed approach to building a multivariable model from a set of candidate predictors (risk factors).[27] In clinical practice, simpler models are more practicable,[27] and, therefore, developing a simple, interpretable model should be the aim. Because the number of events

TABLE 3 Descriptive Statistics of Events per Group

	Standard Neutral Shoe	Motion-Control Shoe	All
Participants at risk, n	185	187	372
Pronation-related running injuries, n (%)	18 (9.7)	7 (3.7)	25 (6.7)
Other running injuries, n (%)	42 (22.7)	26 (13.9)	68 (18.3)
Right censored, n (%)	125 (67.6)	154 (82.3)	279 (75)
Before study end, n (%)	34 (18.4)	58 (31.0)	92 (24.7)
At study end, n (%)	91 (49.2)	96 (51.3)	187 (50.3)
Total time at risk, h	6333	5761	...

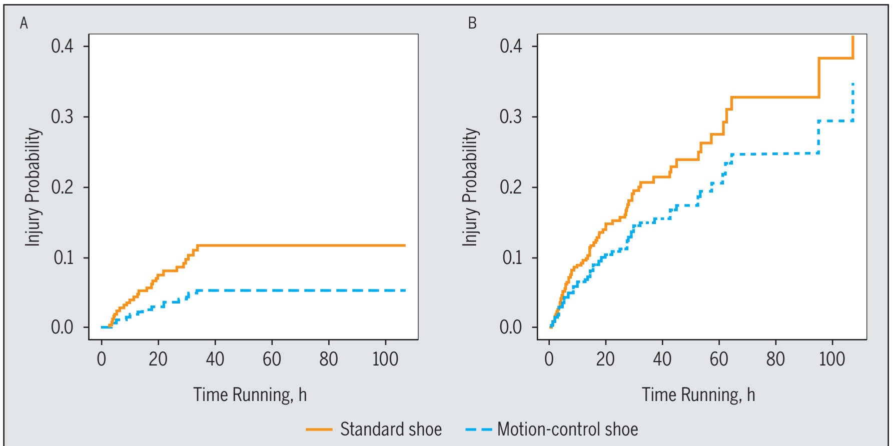

FIGURE. Estimates of the cumulative incidence functions for (A) pronation-related running injuries and (B) other running-related injuries for standard and motion-control shoes, based on a proportional hazards model on the cause-specific hazards.

TABLE 4 Estimated Cause-Specific Hazard Ratios for Pronation-Related Running Injuries and Other Running-Related Injuries

	Pronation-Related Running Injuries (n = 25)		Other Running-Related Injuries (n = 68)	
	Hazard Ratio[a]	*P* Value[b]	Hazard Ratio[a]	*P* Value[b]
Shoe type (reference: standard shoe)	0.409 (0.171, 0.980)	.035	0.675 (0.413, 1.103)	.113
Age, y	0.979 (0.942, 1.018)	.291	0.987 (0.964, 1.011)	.292
Sex (reference: male)	0.912 (0.403, 2.064)	.824	1.055 (0.649, 1.715)	.830
Body mass index, kg/m^2	1.036 (0.912, 1.177)	.590	1.087 (1.007, 1.173)	.035
Previous injury (reference: no previous injury)	4.586 (2.078, 10.12)	<.001	2.273 (1.377, 3.751)	.002
Foot morphology (reference: neutral)				
Supinated/highly supinated	1.639 (0.577, 4.655)	.353	1.152 (0.588, 2.259)	.680
Pronated/highly pronated	1.702 (0.696, 4.163)	.244	1.226 (0.700, 2.148)	.475
Regularity (last 12 mo), mo	0.888 (0.741, 1.064)	.225	0.901 (0.804, 1.009)	.087
Running experience, y	0.982 (0.937, 1.028)	.417	0.996 (0.971, 1.022)	.763
Mean session distance, km	0.943 (0.809, 1.099)	.437	0.883 (0.799, 0.976)	.012
Mean session duration, min	0.995 (0.970, 1.020)	.678	0.990 (0.973, 1.007)	.212
Mean session intensity, AU	0.911 (0.594, 1.397)	.666	0.915 (0.707, 1.185)	.496
Running frequency, sessions per week	0.834 (0.515, 1.352)	.440	0.763 (0.566, 1.028)	.057
Other sports frequency, sessions per week	1.018 (0.777, 1.335)	.897	1.040 (0.892, 1.214)	.622

Abbreviation: AU, arbitrary unit.
[a]*Values in parentheses are 95% confidence interval.*
[b]*For univariable likelihood ratio tests.*

TABLE 5 Results of Modeling the Cause-Specific Hazard for Pronation-Related Running Injuries and Other Running-Related Injuries

	Hazard Ratio[a]	*P* Value
Pronation-related running injuries (n = 25)		
Shoe type (reference: standard shoe)	0.411 (0.171, 0.986)	.047
Previous injury (reference: no previous injury)	4.976 (2.241, 11.046)	<.0001
Other running-related injuries (n = 68)		
Previous injury (reference: no previous injury)	2.270 (1.365, 3.776)	.002
Mean session distance, km	0.886 (0.798, 0.984)	.024

[a]*Values in parentheses are 95% confidence interval.*

of interest was limited (25 runners with pronation-related running injuries), and it is recommended not to use more than 1 predictor per 10 injuries,[23] the full model approach and backward elimination approach were inadequate. Predictors already reported in the literature would normally be the best candidates.

Because injury history is the most well-known predictor for a new injury[10] and this variable was highly associated with the development of pronation-related running injuries in the unadjusted analysis, we entered injury history first in the multivariable model. The second strongest association observed in the unadjusted models was the intervention. We added shoe type as the second variable in the model. The effect of adding other predictors separately was tested but did not show any improvement to the model, based on the Akaike information criterion. Automatic stepwise model building via forward selection identified the same final model. As foot morphology is a risk factor for lower-limb overuse injuries,[18] we stratified randomization and investigated the effect of foot morphology. The HRs for different foot morphology strata[15] might have given more information. However, the sample size and the number of pronation-related running injuries were too small to represent this interaction adequately. Although the distribution of neutral, pronated, and supinated foot types in the pronation-related running injury, other RRI, and uninjured groups was slightly unbalanced, with somewhat fewer neutral foot types in the pronation-related running injury group (neutral: 48%, 57%, 59%; pronated: 32%, 26%, 24%; supinated: 20%, 16%, 16%, respectively), the unadjusted univariable hazard of foot morphology was assessed, and no effect could be established.

Classifying Injuries Based on Pathophysiological Mechanism

Accurately defining the event of interest was not always easy. Diagnosis was based on a detailed process of injury information retrieval. The self-reported information in the internet-based platform was cross-validated by phone by a member of the research team (a sport scientist with 15 years of experience). When the participant consulted a physician or other (para)medic for his or her complaints, the participant was asked to report the diagnosis and any additional relevant information as accurately as possible to the research team. At the end of the study, when all participants returned their shoes to the laboratory, a final verification was performed to detect any inconsistency or missing information related to injury. Based on all provided information, a member of the research team (a physical therapist with 20 years of experience) dichotomized the injuries as pronation related or not pronation related.

To identify homogeneous subgroups of injuries like pronation-related running injuries, the mechanisms in the development of those injuries should be known. A weakness of our study is that the pathophysiological mechanisms of the pronation-related running injury were based on theoretical assumptions. It is possible that we overlooked other pathologies that are also related to pronation, but for which the underlying mechanism is not clear based on current evidence. Misclassification could thus have occurred, introducing bias in effect estimates,[30] and should be considered when drawing conclusions. Because the pathophysiological mechanism is still unclear for many sports injuries, further research should focus on identifying and unraveling the etiology of running injuries.

Beware of Shoe Classification

Comparing our results with other studies is difficult due to differences in design, population, outcome measures, and shoe characteristics. In previous studies, neutral running shoes had some motion-control features,[21,28] while the neutral shoes used in our trial had no motion-control technology at all. There is currently no consensus on the classification of running shoes.

Evaluate the Censoring Mechanism

There was an imbalance in the number of participants right censored before the end of the study. Reasons for dropout were adequately registered, and the censoring mechanism was not directly related to the shoe model. However, more participants in the motion-control shoe group dropped out because of lack of motivation and other non-RRIs. Censored participants could have had a higher risk for RRIs in general. Informative censoring could therefore not be ruled out. Future studies should try to adequately register the reasons for dropout and evaluate the censoring mechanism.

Limitations

The sample-size calculation in the original trial was performed based on the expected difference in the amount of any type of running injury between the two shoe-type groups, and yielded a total sample of 364 runners. In our secondary analysis, data were categorized into different types of injuries, and only 25 injuries were identified as pronation-related running injuries. Although we found statistically significant effects for shoe type and previous injury, our analysis was underpowered to present stratified analysis results based on foot morphology. Therefore, our results should be seen as preliminary.

CONCLUSION

Wearing motion-control shoes reduced the risk of pronation-related running injuries in middle-aged recreational runners, but not the risk of other RRIs. Accounting for the underlying injury mechanism (using competing risk analysis) and specifically targeting injury types that might benefit from the intervention were more accurate for estimating treatment effect than lumping all injury types. ◉

KEY POINTS

FINDINGS: Motion-control shoes reduced the risk of pronation-related running injuries in regularly active recreational runners, but had little or no protective effect on other running-related injuries.
IMPLICATIONS: Clinicians might consider prescribing motion-control shoes for runners who are prone to Achilles tendinopathy, plantar fasciopathy, exercise-related lower-leg pain, and anterior knee pain.
CAUTION: Misclassification of injuries could have resulted in bias. The number of events of interest (injuries) was limited, and the conclusions need to be confirmed by future work.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: All authors contributed to the study concept and research design; the analysis and interpretation of data; and the writing, review, and editing of the manuscript, and all authors gave final approval of the manuscript. Drs Malisoux, Theisen, and Willems acquired the data. Drs Malisoux and Theisen secured funding, provided facilities and equipment, and recruited participants. Dr Willems takes responsibility for the integrity of the work as a whole, from inception to published article.
DATA SHARING: There are no data available.
PATIENT AND PUBLIC INVOLVEMENT: There was no patient and public involvement in this research.

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APPENDIX

PREDEFINED LIST OF INJURY TYPES IN THE INTERNET-BASED PLATFORM (WWW.TIPPS.LU)

- Unknown
- Fracture
- Other traumatism (bone tearing, Osgood-Schlatter, Sinding-Larsen-Johansson, sever, periostitis)
- Luxation/dislocation
- Sprain/torn ligaments/minor problems with joint capsules
- Meniscal, joint cartilage, or spinal disc lesion
- Muscles: pain/spasm/cramp/strain/muscle tear
- Tendon: tear/tendinitis/tenosynovitis/bursitis
- Hematoma/effusion of blood/bruise
- Scratch/graze/abrasion
- Skin tear/cut
- Concussion (with or without loss of consciousness)
- Injury of peripheral nervous system
- Injury of central nervous system
- Teeth: disorders/injuries
- Internal organs
- Other injuries

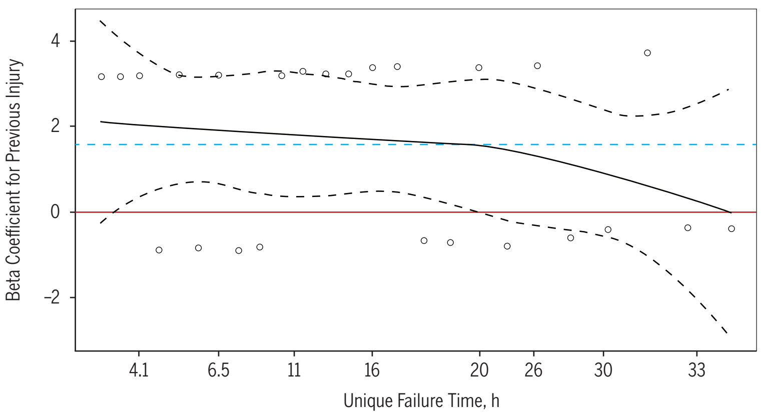

FIGURE. Plot of the coefficient and Schoenfeld residuals for previous injury history in the Cox model for pronation-related running injuries. The solid black line represents the estimated beta coefficient over time, and the dotted lines represent its 95% confidence interval. The open circles represent the Schoenfeld residuals. The horizontal blue dashed line is the coefficient if proportionality of hazards is assumed.