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Influence of the Heel-to-Toe Drop of Standard Cushioned Running Shoes on Injury Risk in Leisure-Time Runners

A Randomized Controlled Trial With 6-Month Follow-up

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Background: Modern running shoes are available in a wide range of heel-to-toe drops (ie, the height difference between the forward and rear parts of the inside of the shoe). While shoe drop has been shown to influence strike pattern, its effect on injury risk has never been investigated. Therefore, the reasons for such variety in this parameter are unclear.

Purpose: The first aim of this study was to determine whether the drop of standard cushioned running shoes influences running injury risk. The secondary aim was to investigate whether recent running regularity modifies the relationship between shoe drop and injury risk.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: Leisure-time runners (N = 553) were observed for 6 months after having received a pair of shoes with a heel-to-toe drop of 10 mm (D10), 6 mm (D6), or 0 mm (D0). All participants reported their running activities and injuries (time-loss definition, at least 1 day) in an electronic system. Cox regression analyses were used to compare injury risk between the 3 groups based on hazard rate ratios (HRs) and their 95% CIs. A stratified analysis was conducted to evaluate the effect of shoe drop in occasional runners (<6 months of weekly practice over the previous 12 months) versus regular runners (≥6 months).

Results: The overall injury risk was not different among the participants who had received the D6 (HR, 1.30; 95% CI, 0.86-1.98) or D0 (HR, 1.17; 95% CI, 0.76-1.80) versions compared with the D10 shoes. After stratification according to running regularity, low-drop shoes (D6 and D0) were found to be associated with a lower injury risk in occasional runners (HR, 0.48; 95% CI, 0.23-0.98), whereas these shoes were associated with a higher injury risk in regular runners (HR, 1.67; 95% CI, 1.07-2.62).

Conclusion: Overall, injury risk was not modified by the drop of standard cushioned running shoes. However, low-drop shoes could be more hazardous for regular runners, while these shoes seem to be preferable for occasional runners to limit injury risk.

Keywords: sports injury prevention; footwear; epidemiology

Despite advances in running shoe technology and the constant development of new concepts, the effect of specific footwear features on the risk of running-related injury has received surprisingly little attention from the scientific community.[22,30] Only a few studies have tested the effect of single shoe features, such as midsole hardness[27] or motion control systems.[11,24] Others have investigated whether the use of minimalist shoes specifically designed to mimic barefoot running is associated with injury risk.[7,21,23] Despite a lack of consensus across these studies regarding the definition, minimalist shoes are generally characterized by low weight, high flexibility, low cushioning, little or no motion control, wide toe-box, limited stack height, and a reduced shoe drop (ie, the height difference between the rearfoot and forefoot).[4] Minimalist shoes are available in a wide range of drops—from 0 mm to 8 mm—while

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conventional cushioned running shoes are designed with a 10- to 12-mm drop. Such high shoe drops have been associated with higher foot-ground angle (ie, a more pronounced rearfoot strike) and lower knee flexion angle at touchdown, as well as less ankle joint flexion at midstance phase, compared with low drop.[2] However, the mere effect of shoe drop on running performance and running economy has not been investigated independently of other shoe properties such as shoe mass.[6] Why manufacturers use such a high drop is unclear.

To date, no studies have specifically focused on the association between shoe drop and injury risk.[17] Thus, the only information available on this topic can be extrapolated from comparisons between minimalist and conventional running shoes, although confounding may be present due to other differences. A retrospective study showed that runners wearing minimalist shoes reported fewer lower extremity injuries than runners using traditional shoes.[7] However, the results should be interpreted with caution, because of the retrospective design and because the reliance on a convenience sample of minimalist shoe users introduces a potential bias. By contrast, a randomized controlled trial on habitual recreational runners revealed that the use of partial and full minimalist shoes resulted in an increased injury risk compared with conventional shoes.[23] Also, the risk of bone marrow edema in the foot was increased after the transition to minimalist shoes.[21] These contrasting results could be due to differences in design and study population and, most of all, the lack of consensus on minimalist shoe definition.[4] Whether shoe drop is related to injury risk cannot be extrapolated from these studies, and, as recently reiterated,[25] more research on the effect of single shoe features is clearly warranted. Because the runner's profile and especially running history (eg, long-term experience or recent running regularity) have been shown to influence injury incidence,[31] injury locations,[10] and injury mechanisms,[14] the effect of shoe drop on injury risk may be specific to the population investigated.

Therefore, the aim of this study was to determine whether the drop of standard cushioned running shoes affects injury risk, as well as to investigate whether the relationship between shoe drop and injury risk is influenced by recent running regularity. To isolate the effect of shoe drop from other features, we compared different versions of conventional shoes with either a standard drop (10 mm, D10) or no drop (0 mm, D0). Since an increasing number of available running shoes have a drop between 4 and 8 mm, a third version with 6-mm shoe drop (D6) was also tested. Given the results of a previous study,[23] we hypothesized that a low drop is associated with higher injury risk. Our secondary hypothesis was that the effect of a lower shoe drop on injury risk depends on recent running regularity.

METHODS

Participants and Study Design

Reporting of the study followed the CONSORT statement (see the Appendix, available in the online version of this article and at http://ajsm.sagepub.com/supplemental).[16] This randomized controlled trial included leisure-time runners, regardless of their fitness level or running experience. We determined that with an alpha of .05, a power of 80%, an average injury rate of 30%,[15,30] an expected hazard rate ratio (HR) of 1.75 between the extreme models (D10 and D0),[23] 33% of the participants randomized to each shoe group, and an expected dropout rate of 10%, a total number of 535 participants needed to be recruited to compare injury risk between the study groups. All volunteers received a full description of the study protocol and provided written informed consent for participation. All procedures were approved by the National Ethics Committee for Research (ref. 201407/09). The participants were recruited via advertisements in local newspapers from September to December 2014. Volunteers registered for the study and made an appointment with the research team via a dedicated website. Volunteers also completed an online questionnaire regarding age, sex, running regularity over the previous 12 months (months of practice), running experience (years of regular practice), and previous injury to the lower back or lower limbs that prevented normal running activity and was sustained during the 12 months preceding the study. Inclusion criteria were good health, age 18 to 65 years, no prior (last 12 months) use of minimalistic running shoes with drop less than 4 mm, no contraindication to perform running activity, no prior (<12 months) surgery of the lower limbs or lower back region, and no use of orthopaedic insoles for running. Volunteers were also required to perform at least 1 running activity per week during the 6-month follow-up period, to use the provided study shoes for all running activities, and to report at least once per week all sports activities and injury or pain experienced during the follow-up. No particular training program was enforced. Eligibility and responses to the baseline questionnaire were checked during a first laboratory visit. The participants were classified as occasional (<6 months) or regular runners ($\geq$6 months) according to the months of regular practice over the previous 12 months.[14,27] Additionally, the participants presented all their running shoes used over the previous 12 months so the research team could classify the shoes according to their drop, based on information retrieved from the Internet (shoe specifications on official websites or other websites when the information was missing). Participants who presented a pair of shoes with a drop less than 10 mm were classified as participants with previous experience with low-drop running shoes.

Study Shoe Characteristics

The study shoes were prototypes derived from an Eliorun provided by Kalenji and anonymized for the purpose of this trial. The shoes were available in 3 versions that were identical except for the height of the sole at the heel and the forefoot, modified to generate the predefined shoe drops. The heights of the sole at the heel and the forefoot were, respectively, as follows: 24 and 14 mm in D10; 21 and 15 mm in D6; and 21 and 21 mm in D0. Differences between the 3 versions regarding cushioning properties at

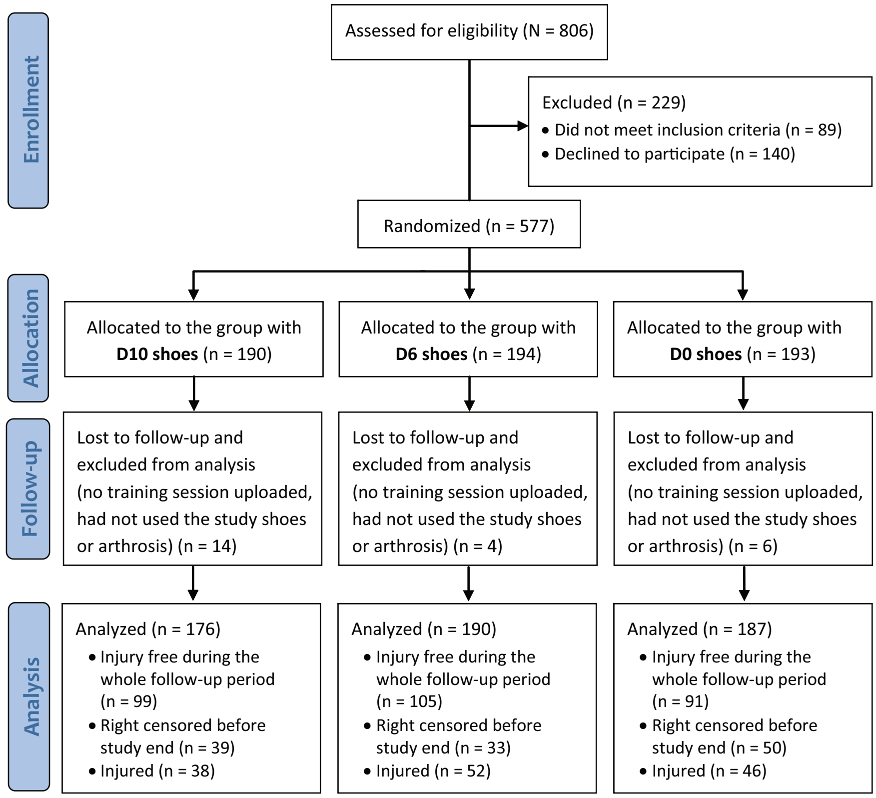

Figure 1. Flowchart of the volunteers and participants.

the heel were less than 15%, which was inconsequential for injury risk.[27] Previous experience with low-drop running shoes (low-drop experience) was suggested to be a confounding factor for injury risk.[3] Therefore, at the moment of recruitment, eligible participants were stratified according to their low-drop experience (<10 mm). Two preestablished randomization lists (block size = 60) were thus used to allocate the 3 shoe versions randomly to the participants. Each shoe pair was coded by a coworker not involved in the study before the distribution. Participants and the investigators in charge of the follow-up and data validity check were blinded regarding the shoe version distributed. The shoe code was broken after completion of data collection.

Data Collection During Follow-up

Participants' information regarding their sports participation as well as any adverse events (injuries, pain, and illnesses) was collected via an Internet-based platform (http://www.tipps.lu; Training and Injury Prevention Platform for Sports).[13,15,27] Required information about training sessions included the type of activity, duration of session, subjectively perceived intensity (on a 0-10 scale, 10 being highest), distance covered, running surface, shoe pair used, and whether the participant had experienced any pain during the session.[11-13] Injuries were self-declared in the system and were defined as any physical pain located at the lower limbs or lower back region, sustained during or as a result of running practice and impeding planned running activity for at least 1 day (time-loss definition). They were then classified according to consensus guidelines on sports injury surveillance studies[5,28] by use of a previously described questionnaire.[12,15]

Every self-reported injury was checked by the research team for completeness and coherence. A participant was considered as dropping out of the study when no data were uploaded in the system for more than 2 weeks despite an automatic email reminder. These participants were contacted to ensure that injury was not the reason for noncompliance. At the end of the study (May 2015), the participants were contacted via phone call or email for a final check of all data regarding injury, compliance, and shoe use.

Statistical Analyses

Descriptive data for personal and training-related characteristics are presented as count and percentage for dichotomous variables and as mean and standard deviation or median and range, respectively, for normally and nonnormally distributed continuous variables. Average sport-related characteristics were computed for each participant over her or his individual period of observation. Cox proportional hazards regression was used to compute the hazard rates in the exposure groups, using first-time injury as the primary outcome.

TABLE 1
Participant Characteristics and Sport Participation Pattern for the 3 Study Groups[a]

	D10 Group (n = 176)	D6 Group (n = 190)	D0 Group (n = 187)
Participant characteristics			
Age, y	38.3 ± 9.7	38.0 ± 9.6	38.6 ± 9.9
Sex, n (%)			
Male	106 (60)	111 (58)	124 (66)
Female	70 (40)	79 (42)	63 (34)
Body mass index, kg/m^2	23.8 ± 3.1	23.9 ± 3.3	24.0 ± 3.3
Previous injury, n (%)			
No	132 (75)	146 (77)	145 (77)
Yes	44 (25)	44 (23)	42 (23)
Running experience, y, median (range)	8 (0-39)	7 (0-40)	8 (0-47)
Running regularity, n (%)			
Occasional	44 (25)	55 (29)	51 (27)
Regular	132 (75)	135 (71)	136 (73)
Low-drop experience, n (%)[b]			
No	136 (77)	148 (78)	147 (79)
Yes	42 (24)	42 (22)	40 (21)
Sport participation pattern			
Sessions run with study shoes, % of total sessions	97.7 ± 7.2	98.7 ± 4.6	98.3 ± 6.4
Other sports, sessions/wk	0.7 ± 1.0	0.8 ± 1.1	0.9 ± 1.5
Running frequency, sessions/wk	1.6 ± 1.1	1.5 ± 1.0	1.8 ± 1.7
Session duration, min	51 ± 15	50 ± 16	50 ± 16
Session distance, km	8.0 ± 2.8	7.9 ± 3.0	7.9 ± 3.2
Session intensity[c]	3.6 ± 0.9	3.7 ± 0.9	3.6 ± 0.9
Speed, km/h	9.5 ± 1.6	9.4 ± 1.5	9.6 ± 1.6
Running on hard surface, % of total sessions	65.6 ± 30.9	63.2 ± 32.8	59.6 ± 33.5
Competition, % of total volume	1.0 ± 2.7	1.7 ± 4.2	1.2 ± 3.6

[a]Data are reported as mean ± SD unless otherwise indicated. Groups were stratified according to shoes with a heel-to-toe drop of 10 mm (D10), 6 mm (D6), or 0 mm (D0).
[b]Regularly used running shoes with heel-to-toe drop of less than 10 mm over the previous 12 months.
[c]Graded on a 0-10 scale, 10 being highest.

Date of inclusion (shoe distribution date) and date of injury or of censoring were basic data used to calculate the time at risk. The latter was expressed in hours spent running and was used as the time-scale.[18] A participant was right-censored, yet included in the analyses, in case of severe disease, if injury unrelated to running caused a modification of the running plan, or at the end of follow-up, whichever came first. To validate the statistical model, the assumption of proportional hazards was evaluated by log-minus-log plots.

To address the primary objective, unadjusted Cox regressions were performed to present the crude estimates of HRs for shoe model and other potential risk factors. Then, the variables with a P value less than .200 were included in the adjusted Cox regression analysis to determine whether shoe drop was associated with injury risk, controlling for potential confounders. The recommendation for using at least 10 injuries per predictor variable included in the Cox regression analysis was strictly followed.[19]

To address the secondary objective, the cohort was stratified according to running regularity (occasional vs regular runners). Runners were classified as occasional (<6 months) or regular runners (≥6 months) according to the months of regular practice over the previous 12 months.[14,27] HRs and their 95% CIs were determined within each stratum with unadjusted Cox regression analyses. Given that the aim of the secondary analysis was to investigate the effect of running shoes with lower drops on injury risk in these subpopulations, the participants who received the low-drop versions (D6 and D0) were grouped together and compared with the conventional shoes (D10) for this analysis. Significance was accepted for $P < .05$. All analyses were performed with SPSS V20.

RESULTS

Participants

Of the 806 volunteers who registered via the online questionnaire, 577 came to the laboratory, fulfilled the inclusion criteria, were randomly allocated to one of the study groups, and received a pair of running shoes (Figure 1). Twenty-four participants were lost during the follow-up and were excluded from the analyses because they did not upload any training data (n = 10), had suffered from blisters in the first session and stopped participation (n = 5), had health problems unrelated to running (n = 5), were diagnosed with arthrosis (n = 2), or dropped out for personal reasons (n = 2). Their demographics were similar to those of the 553 participants included in the analyses (see Appendix Table A1). Only 29 participants (5%) had used shoe models from the same brand as the study shoes before the intervention.

The participants recorded a total of 14,788 running sessions (127,608 km). Overall, the compliance regarding the use of the provided study shoes was high (98.2%). The group characteristics are presented in Table 1.

Injuries

A total of 136 participants (25%) sustained an injury during the follow-up. The proportions of injured participants were 21.6%, 27.4%, and 24.6% in the D10, D6, and D0 groups, respectively. The overall incidence was 10.33 injuries per 1000 hours of running (95% CI, 10.28-10.39). Table 2 presents the characteristics of the self-reported injuries.

TABLE 2
Characteristics of Self-Reported Injuries for Each Study Group (n = 136)[a]

	D10 Group (n = 38)	D6 Group (n = 52)	D0 Group (n = 46)
Injury location			
Lower back region/pelvis	2 (5.3)	2 (3.8)	2 (4.3)
Hip/groin	1 (2.6)	2 (3.8)	1 (2.2)
Thigh	0 (0)	4 (7.7)	2 (4.3)
Knee	9 (23.7)	15 (28.8)	7 (15.2)
Lower leg	13 (34.2)	13 (25.0)	15 (32.6)
Ankle	10 (26.3)	6 (11.5)	10 (21.7)
Foot	2 (5.3)	10 (19.2)	9 (19.6)
Toe	1 (2.6)	0 (0)	0 (0)
Injury type			
Tendon	19 (50.0)	29 (55.8)	24 (52.2)
Muscle	11 (28.9)	15 (28.8)	16 (34.8)
Capsules and ligaments	5 (13.2)	3 (5.8)	3 (6.5)
Bone structures	2 (5.3)	1 (1.9)	3 (6.5)
Other joint structures	1 (2.6)	4 (7.7)	0 (0)
Injury severity			
Slight (0-3 days)	9 (23.7)	5 (9.6)	12 (26.1)
Minor (4-7 days)	6 (15.8)	12 (23.1)	6 (13.0)
Moderate (8-28 days)	11 (28.9)	12 (23.1)	17 (37.0)
Major (>28 days)	12 (31.6)	23 (44.2)	11 (23.9)
Recurrence			
No	28 (73.7)	29 (55.8)	34 (73.9)
Yes	10 (26.3)	23 (44.2)	12 (26.1)
Injury category			
Acute	7 (18.4)	3 (5.8)	4 (8.7)
Progressive	31 (81.6)	49 (94.2)	42 (91.3)

[a]Data are reported as n (%).

Primary Analysis

None of the shoe models with reduced drop (D6 and D0) were associated with injury risk when compared with D10 (P = .223 and P = .499, respectively) (Table 3). In the adjusted regression model, previous injury (P = .012) and weekly running frequency ($P < .001$) were identified as risk factors, whereas running duration ($P < .001$) was a protective factor. Since both adjusted and unadjusted regression models yielded very similar estimates for the shoe versions, crude estimates were used in the stratified analyses.

Secondary Analyses

The stratified analysis revealed that in the group of occasional runners, the rate at which the injuries occurred was lower among those using low-drop shoe versions (HR, 0.48; 95% CI, 0.23-0.98), whereas in the group of regular runners the injury rate was higher (HR, 1.67; 95% CI, 1.07-2.62) (Table 4).

DISCUSSION

This randomized controlled trial aimed to determine whether the drop of conventional running shoes influences injury risk. We found that overall, shoe drop was not associated with injury risk. Our secondary aim was to investigate whether the relationship between shoe drop and injury risk was influenced by running regularity. The stratified analysis showed that in occasional runners, injury risk was lower among those who received low-drop shoe versions (D6 and D0), while in regular runners, injury risk was higher among those who received low-drop versions.

Previous reports have analyzed the effect of single shoe characteristics on injury risk, such as midsole hardness[27] or motion control features.[11] However, no prior investigation has specifically focused on shoe drop. The latter characteristic is typical for minimalist footwear. Prior studies have compared conventional with minimalist shoes and showed conflicting results regarding the relationship between shoe model and injury risk.[1,7,21,23] However, both shoe types often differ in many aspects, thus preventing identification of particular shoe characteristics that could influence injury risk. Additionally, the term *minimalist* has been used without standardization for decades, and a consensus on the features that define minimalist running shoes has only recently been suggested.[4] This could partially explain the lack of consistency between study results.

Both occasional and recreational runners were included in this study. Therefore, the overall incidence (10.3 injuries per 1000 h of exposure) is in line with the weighted estimates for novice runners (17.8 injuries per 1000 h) and recreational runners (7.7 injuries per 1000 h) presented in a systematic review.[31] Also, the risk factors identified in this study are consistent with previous observations. Previous injury was identified as a consistent risk factor,[30] and so was session frequency, as found by several prospective cohort studies.[14,26,32] Since many experts consider that most running injuries are related to training characteristics, and are therefore preventable,[9,18] we also investigated whether mean session intensity and duration were associated with injury risk. In our study, only mean session duration was a protective factor. The literature contains conflicting results regarding the association between running volume and injury risk.[14,20,30] This could arise from

TABLE 3
Results of the Unadjusted and Adjusted Cox Regression Models for the Variables Tested (N = 553)[a]

	Unadjusted Model		Adjusted Model	
	HR	*P* value	HR	95% CI
Shoe version (*ref* = D10)[b]				
D6	1.29	.239	1.30	0.86-1.98
D0	1.21	.392	1.17	0.76-1.80
Participant characteristics				
Age, y	1.00	.781		
Sex (*ref* = male)	1.23	.246		
BMI (1 kg/m^2 increase)	1.01	.736		
Previous injury (*ref* = no injury)	1.54	.018[c]	1.59[d]	1.11-2.28
Running experience, y	1.00	.835		
Running regularity (*ref* = regular)	1.29	.212		
Low-drop experience (*ref* = no experience)[e]	0.75	.154[c]	0.77	0.49-1.20
Sport participation pattern				
Other sports frequency, sessions/wk	1.06	.412		
Running frequency, sessions/wk	1.29	<.001[c]	1.28[d]	1.17-1.41
Mean session duration, min	0.98	<.001[c]	0.97[d]	0.96-0.99
Mean session intensity[f]	1.01	.904		

[a]BMI, body mass index; HR, hazard ratio; *ref*, reference.
[b]Shoe versions included heel-to-toe drop of 10 mm (D10), 6 mm (D6), or 0 mm (D0).
[c]Variables with *P* value less than .200 were included in the adjusted model; total volume of exposure was 13,160 hours.
[d]Significant results.
[e]Experience with low-drop (<10 mm) running shoes over the previous 12 months.
[f]Graded on a 0-10 scale, 10 being highest.

TABLE 4
Unadjusted Cox Regression Analyses for Occasional and Regular Runners[a]

	Occasional Runners (n = 150; 33 injured)		Regular Runners (n = 403; 103 injured)	
Indicator	HR	95% CI	HR	95% CI
Shoe version (*ref* = D10)[b]				
D6	0.48	0.21-1.10	1.74[c]	1.06-2.86
D0	0.47[d]	0.20-1.12	1.60	0.97-2.66
Conventional vs low-drop versions (D6+D0; *ref* = D10)	0.48[c]	0.23-0.98	1.67[c]	1.07-2.62

[a]HR, hazard ratio.
[b]Shoe versions included heel-to-toe drop of 10 mm (D10), 6 mm (D6), or 0 mm (D0).
[c]Significant results.
[d]Only 9 injuries were observed in this subgroup.

the possible interaction with the runner's fitness, experience, or other personal characteristics.

Plausible explanations for the absence of a global effect of shoe drop on injury risk are difficult to provide since no prior study has investigated this association. One biomechanical study showed that changes in shoe drop between 0 and 8 mm influenced ground-reaction forces and joint angles during running,[2] which could alter injury risk. Nevertheless, the shoes used in that study were prototypes with limited cushioning properties, whereas the 3 versions tested here were derived from a standard cushioned shoe. Another study showed that foot-strike pattern was acutely changed as a result of a combined modification of shoe drop and stack height at the heel,[8] but the 2 characteristics were not investigated independently. Thus, on the basis of our primary analysis, it could be speculated that the absence of shoe drop effect on injury risk was related to the cushioning properties, allowing the participants to maintain their usual running technique, whatever the drop. Biomechanical studies are needed to investigate the influence of the drop of cushioned shoes on running style.

Running is practiced by many people with varying backgrounds in terms of sports history, running experience, fitness level, and age. Thus, despite an overall neutral effect of shoe drop on injury risk, the relationship could actually be population-specific, as revealed by our secondary analysis and already suggested for other risk factors.[14,29] A systematic review presented differences in risk profile between men and women.[29] Similarly, it was shown that the training load a runner is able to tolerate is affected by previous injury and body mass index.[14] The present results suggest that the effect of shoe drop on injury risk depends on the runner's training regularity over the past 12 months. Based on the secondary analysis, it seems safe to recommend low-drop footwear for occasional or unexperienced runners. In contrast, regular runners with low-drop shoes appeared to be at a higher risk compared with those who received conventional shoes. Since the participants were required to use the study shoes for all their running sessions, it could be speculated that in regular runners, the transition from their usual running shoes (about 78% of the participants did not use low-drop running shoes before the study) to the low-drop versions (D6 or D0) was not progressive enough and increased injury risk.[22] One might expect that runners with a certain amount of running experience and well-adapted musculoskeletal system are suitable candidates for low-drop shoes, but safe transition could actually require a longer period.

The main limitation of this study is that the size of the groups was unbalanced after stratification according to running regularity (Table 4). Also, this study was initially not powered for the secondary hypothesis. Therefore, the absence of significant results for the comparison between D10 and D0 versions in each stratum may be due to insufficient statistical power and should be taken with caution (Table 4). However, after grouping D6 and D0 shoe versions, we met the general rule requiring 10 events of interest (ie, injuries) per variable.[19] Another point is that our participants may not be representative of the whole population of leisure-time runners. Some may have declined to participate, for example, because they prefer to rotate between several shoe pairs or because they have negative experience with low-drop shoes. A further aspect is that categorizing those participants who declared regular running activity around our cut-off (6 months during the prior year) may have been imprecise. The study protocol was designed to blind the participants regarding the shoe version they received. However, while the investigators responsible for the follow-up of the participants and data quality check were blinded, it is reasonable to assume that the participants could find out whether they received a version with a lower drop than their usual running shoes. Last, the study could have benefited from an analysis of the running biomechanics of our participants. However, this was not done given the organizational implications of that approach with such a large sample size.

CONCLUSION

Overall, the injury risk was not modified by the drop of standard cushioned running shoes. However, the runner's profile could be a key factor when deciding on the use of low-drop running shoes, since the secondary analysis revealed that in occasional runners, low-drop shoes were associated with a lower injury risk, while they were associated with a higher injury risk in regular runners.

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REFERENCES

1. Altman AR, Davis IS. Prospective comparison of running injuries between shod and barefoot runners. *Br J Sports Med*. 2016;50(8):476-480.
2. Chambon N, Delattre N, Gueguen N, Berton E, Rao G. Shoe drop has opposite influence on running pattern when running overground or on a treadmill. *Eur J Appl Physiol*. 2015;115(5):911-918.
3. Cheung RT, Ngai SP. Effects of footwear on running economy in distance runners: a meta-analytical review. *J Sci Med Sport*. 2016;19(3):260-266.
4. Esculier JF, Dubois B, Dionne CE, Leblond J, Roy JS. A consensus definition and rating scale for minimalist shoes. *J Foot Ankle Res*. 2015;8:42.
5. Fuller CW, Ekstrand J, Junge A, et al. Consensus statement on injury definitions and data collection procedures in studies of football (soccer) injuries. *Br J Sports Med*. 2006;40(3):193-201.
6. Fuller JT, Bellenger CR, Thewlis D, Tsiros MD, Buckley JD. The effect of footwear on running performance and running economy in distance runners. *Sports Med*. 2015;45(3):411-422.
7. Goss DL, Gross MT. Relationships among self-reported shoe type, footstrike pattern, and injury incidence. *US Army Med Dep J*. Oct-Dec 2012:25-30.
8. Horvais N, Samozino P. Effect of midsole geometry on foot-strike pattern and running kinematics. *Footwear Sci*. 2013;5(2):81-89.
9. Hreljac A. Etiology, prevention, and early intervention of overuse injuries in runners: a biomechanical perspective. *Phys Med Rehabil Clin N Am*. 2005;16(3):651-667, vi.
10. Kluitenberg B, van Middelkoop M, Diercks R, van der Worp H. What are the differences in injury proportions between different populations of runners? A systematic review and meta-analysis. *Sports Med*. 2015;45(8):1143-1161.
11. Malisoux L, Chambon N, Delattre N, Gueguen N, Urhausen A, Theisen D. Injury risk in runners using standard or motion control shoes: a randomised controlled trial with participant and assessor blinding. *Br J Sports Med*. 2016;50(8):481-487.
12. Malisoux L, Frisch A, Urhausen A, Seil R, Theisen D. Injury incidence in a sports school during a 3-year follow-up. *Knee Surg Sports Traumatol Arthrosc*. 2013;21(12):2895-2900.
13. Malisoux L, Frisch A, Urhausen A, Seil R, Theisen D. Monitoring of sport participation and injury risk in young athletes. *J Sci Med Sport*. 2013;16(6):504-508.
14. Malisoux L, Nielsen RO, Urhausen A, Theisen D. A step towards understanding the mechanisms of running-related injuries. *J Sci Med Sport*. 2015;18(5):523-528.
15. Malisoux L, Ramesh J, Mann R, Seil R, Urhausen A, Theisen D. Can parallel use of different running shoes decrease running-related injury risk? *Scand J Med Sci Sports*. 2015;25(1):110-115.
16. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c869.
17. Murphy K, Curry EJ, Matzkin EG. Barefoot running: does it prevent injuries? *Sports Med*. 2013;43(11):1131-1138.
18. Nielsen RO, Malisoux L, Moller M, Theisen D, Parner ET. Shedding light on the etiology of sports injuries: a look behind the scenes of time-to-event analyses. *J Orthop Sports Phys Ther*. 2016;46(4):300-311.

19. Peduzzi P, Concato J, Feinstein AR, Holford TR. Importance of events per independent variable in proportional hazards regression analysis, II: accuracy and precision of regression estimates. *J Clin Epidemiol*. 1995;48(12):1503-1510.
20. Rasmussen CH, Nielsen RO, Juul MS, Rasmussen S. Weekly running volume and risk of running-related injuries among marathon runners. *Int J Sports Phys Ther*. 2013;8(2):111-120.
21. Ridge ST, Johnson AW, Mitchell UH, et al. Foot bone marrow edema after a 10-wk transition to minimalist running shoes. *Med Sci Sports Exerc*. 2013;45(7):1363-1368.
22. Rixe JA, Gallo RA, Silvis ML. The barefoot debate: can minimalist shoes reduce running-related injuries? *Curr Sports Med Rep*. 2012;11(3):160-165.
23. Ryan M, Elashi M, Newsham-West R, Taunton J. Examining injury risk and pain perception in runners using minimalist footwear. *Br J Sports Med*. 2014;48(16):1257-1262.
24. Ryan MB, Valiant GA, McDonald K, Taunton JE. The effect of three different levels of footwear stability on pain outcomes in women runners: a randomised control trial. *Br J Sports Med*. 2011;45(9):715-721.
25. Squadrone R, Rodano R, Hamill J, Preatoni E. Acute effect of different minimalist shoes on foot strike pattern and kinematics in rearfoot strikers during running. *J Sports Sci*. 2015;33(11):1196-1204.
26. Taunton JE, Ryan MB, Clement DB, McKenzie DC, Lloyd-Smith DR, Zumbo BD. A prospective study of running injuries: the Vancouver Sun Run ''In Training'' clinics. *Br J Sports Med*. 2003;37(3):239-244.
27. Theisen D, Malisoux L, Genin J, Delattre N, Seil R, Urhausen A. Influence of midsole hardness of standard cushioned shoes on running-related injury risk. *Br J Sports Med*. 2014;48(5):371-376.
28. Timpka T, Alonso JM, Jacobsson J, et al. Injury and illness definitions and data collection procedures for use in epidemiological studies in athletics (track and field): consensus statement. *Br J Sports Med*. 2014;48(7):483-490.
29. van der Worp MP, ten Haaf DS, van Cingel R, de Wijer A, Nijhuis-van der Sanden MW, Staal JB. Injuries in runners; a systematic review on risk factors and sex differences. *PloS One*. 2015;10(2):e0114937.
30. van Gent RN, Siem D, van Middelkoop M, van Os AG, Bierma-Zeinstra SM, Koes BW. Incidence and determinants of lower extremity running injuries in long distance runners: a systematic review. *Br J Sports Med*. 2007;41(8):469-480; discussion 480.
31. Videbaek S, Bueno AM, Nielsen RO, Rasmussen S. Incidence of running-related injuries per 1000 h of running in different types of runners: a systematic review and meta-analysis. *Sports Med*. 2015;45(7):1017-1026.
32. Walter SD, Hart LE, McIntosh JM, Sutton JR. The Ontario cohort study of running-related injuries. *Arch Int Med*. 1989;149(11):2561-2564.