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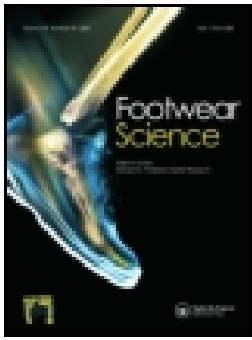
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Changes in the running-related injury incidence rate ratio in a 1000-km explorative prospective cohort study involving two unspecific shoe changes

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A sudden change between any types of running shoes has been suggested to affect the running-related injury incidence rate. The purpose of this project was to investigate how the running-related injury incidence rate ratio (IIRR) modulates during a 1-year explorative prospective cohort study involving two unspecific running shoe changes. Ninety-nine injury-free recreational male runners volunteered to engage in a self-structured running program. At baseline, the runners were provided with a pair of neutral running shoes and were instructed to use these shoes in each running session during the first 500 km of running. Subsequently, the runners had the possibility to switch to other running shoes. When a runner reported an injury, a sports physiotherapist or sports physician recorded it. A total of 30 of the 99 runners sustained at least one running-related injury during the 72.076 km of running with a mean covered distance of 975 (\pm 790 km) per year. The IIRR was calculated as the ratio between the instantaneous injury incidence rate divided by the average injury incidence rate over the follow-up period. In summary, the running-related IIRR was increased above one around the time-points where the runners changed running shoes and decreased below one in the intermediate period. However, it was not possible to confirm that the increased IIRRs were caused by the running shoe changes per se because it could not be excluded that another risk factor, namely the weekly running distance and other unidentified risk factors were involved too. More large-scale studies involving alternative experimental protocols are needed to provide further insight into the association between running-related injury incidence rate and running shoe changes.

Keywords: running; injury aetiology; survival; epidemiology; shoe changes; adaptation

Introduction

Running-related injury is a major barrier that keeps recreational runners from being physically active in running-related activities (Koplan, Rothenberg, & Jones, 1995). In a meta-analysis (Videbaek, Bueno, Nielsen, & Rasmussen, 2015), an incidence rate of 7.7 injuries per 1000 h of running among recreational runners was found.

Consequently, evidence-based initiatives to prevent injuries are of utmost importance. Prevention strategies require knowledge about the aetiology of running-related injuries. However, aetiology of running-related injuries is sparse and needs clarification before it is possible to develop such preventive strategies.

Running shoes and training habits are identified by runners as factors involved in the development of running-related injuries (Saragiotto, Yamato, & Lopes, 2014). However, there are controversies concerning the actual role of running shoes on injury development which have been discussed in the past decade (Malisoux

et al., 2016; Malisoux, Chambon, Urhausen, & Theisen, 2016; Nielsen et al., 2013; Ryan, Valiant, & McDonald, 2011; Theisen et al., 2014).

In several biomechanical studies, kinetics has been demonstrated to change with differences in shoe properties. Peak ground reaction force is increased by a reduction of normal pronation (Perry & LaFortune, 1995), harder midsole (Baltich, Maurer, & Nigg, 2015), changing to new shoes (Rethnam & Makwana, 2011) and using racing flats although not significant (Logan, Hunter, Hopkins, Feland, & Parcel, 2010). In addition, the peak vertical impact peak is reduced by smaller heel-to-toe drop shoes (da Silva Azevedo et al., 2016), conventional running shoes (Logan et al., 2010) and 3 months of adaptation to smaller heel-to-toe drop (Giandolini, Horvais, Farges, Samozino, & Morin, 2013). Moreover, the loading rate is increased by a reduction of normal pronation (Perry & LaFortune, 1995), changing to new shoes (Rethnam & Makwana, 2011), increasing heel-to-toe drop in shoes during

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overground running (Chambon, Delattre, Gueguen, Berton, & Rao, 2015) and using racing flats although only significant for men (Logan et al., 2010). Finally, knee flexion moment during push-off phase is reduced by smaller heel-to-toe drop shoes (Besson, Morio, & Rossi, 2017) while ankle flexion moment is increased by smaller heel-to-toe drop shoes (Besson et al., 2017) and by shoes with a rounded sole in the longitudinal axis (Boyer & Andriacchi, 2009). These results are interesting since they indicate that changes in the mechanical characteristics of running shoes change the total force applied to the body and/or the way the mechanical stress is distributed in the structures of the lower extremities during running. If this is the case, then any change in running shoes without changing running habits may change the distribution of lower extremity tissue loads. An acute redistribution of tissue loads may reveal injurious because the redistribution acutely may load tissues and/or structures above their capacity (Bertelsen et al., 2017; Hreljac, 2005).

Lately, the increase in injury risk immediately after a shoe changes has received considerable attention in the epidemiological literature with emphasis on the change from a conventional running shoe to a minimalistic running shoe. Fuller et al. (2017) found that runners changing to minimalist shoes had more pain compared to runners changing to conventional running shoes. Moreover, Salzler, Bluman, Noonan, Chiodo, & de Asla (2012) found that seven out of ten runners were injured the first 2 months after changing to minimalist shoes and the rest were injured after 3, 4 and 10 months. All injuries occurred in the foot or ankle and nine out of ten were stress fractures. In principle, any shoe change may change the movements and distributions of loads on the structures in the lower extremities during running and therefore potentially increase the risk of sustaining a running-related injury. Therefore, the purpose of this study was to investigate how the running-related injury incidence rate ratio (IIRR) modulates during an explorative prospective cohort study involving two unspecific running shoe changes when using the average injury incidence rate over the follow-up period as reference rate. The first shoe change was compulsory and occurred between the runners preferred running shoes and a standard 'neutral' running shoe provided for all the runners by the research group. The second shoe change was optional and occurred between the provided shoes and shoes free of choice.

It was hypothesised that due to the change of running shoes the IIRR would increase significantly above one after both the compulsory change of running shoes at inclusion and after the optional change of shoes after approximately 500 km when using the

average incidence rate of the follow-up period as reference rate.

Methods

Study design and ethics

The RUNning TECHnique study (RUNTECH) was a prospective cohort study with an approximate 1-year follow-up. The overall purpose was to identify risk factors of running-related injuries. The study is explorative in nature and was designed to shed light on the possible association between changing running shoes and running injury incidence rate. The study was ethically approved by The Ethics Committee of Region Nordjylland, approval number N-20130074 and accepted by the Danish Data Protection Agency, approval number 2008-58-0028. All runners provided written informed consent prior to inclusion and the study was conducted according to the declaration of Helsinki. Reporting follows the STROBE statement (von Elm et al., 2014).

Male runners were recruited in the northern part of Denmark, between February and June 2014. A flowchart of the recruitment process is presented in Figure 1. Recruitment was advertised at local running road races and by e-mail distribution to local companies, hospitals and at the local University. All persons who received an e-mail with information about the study were allowed to forward it to others who might be interested in participating. Within the 5-month of recruitment period, a total of 207 persons signed up for the study by completing an online questionnaire. Inclusion criteria were (1) male between 18 and 60 years, (2) running at least 2 times per week, (3) a minimum of 2 years running experience, (4) no injuries within the past 3 months prior to completing the baseline questionnaire and (5) experienced in treadmill running. Runners were excluded due to (1) no e-mail address or access to the Internet, (2) participation in other sports for more than 4 h a week, (3) use of insoles while running, (4) previous strokes, heart diseases or pain in the chest during training, (5) unwillingness to run in a neutral pair of running shoes or (6) to use a global position system (GPS) watch or smartphone to quantify running during follow-up. Persons eligible for inclusion were contacted by phone for an interview after screening the electronic questionnaire. Runners were invited to a baseline laboratory investigation if they, after the interview, were eligible for inclusion.

Runners were screened for eligibility and their smartphone and/or GPS watches were screened for compatibility with a web-based database (www.mit-løbeprogram.dk) which was used to collect training distance and injury status of the runners. The included runners were prescribed with a pair of conventional 'neutral' running shoes (Asics Gel-pulse5; designed with a heel raise, medial arch support

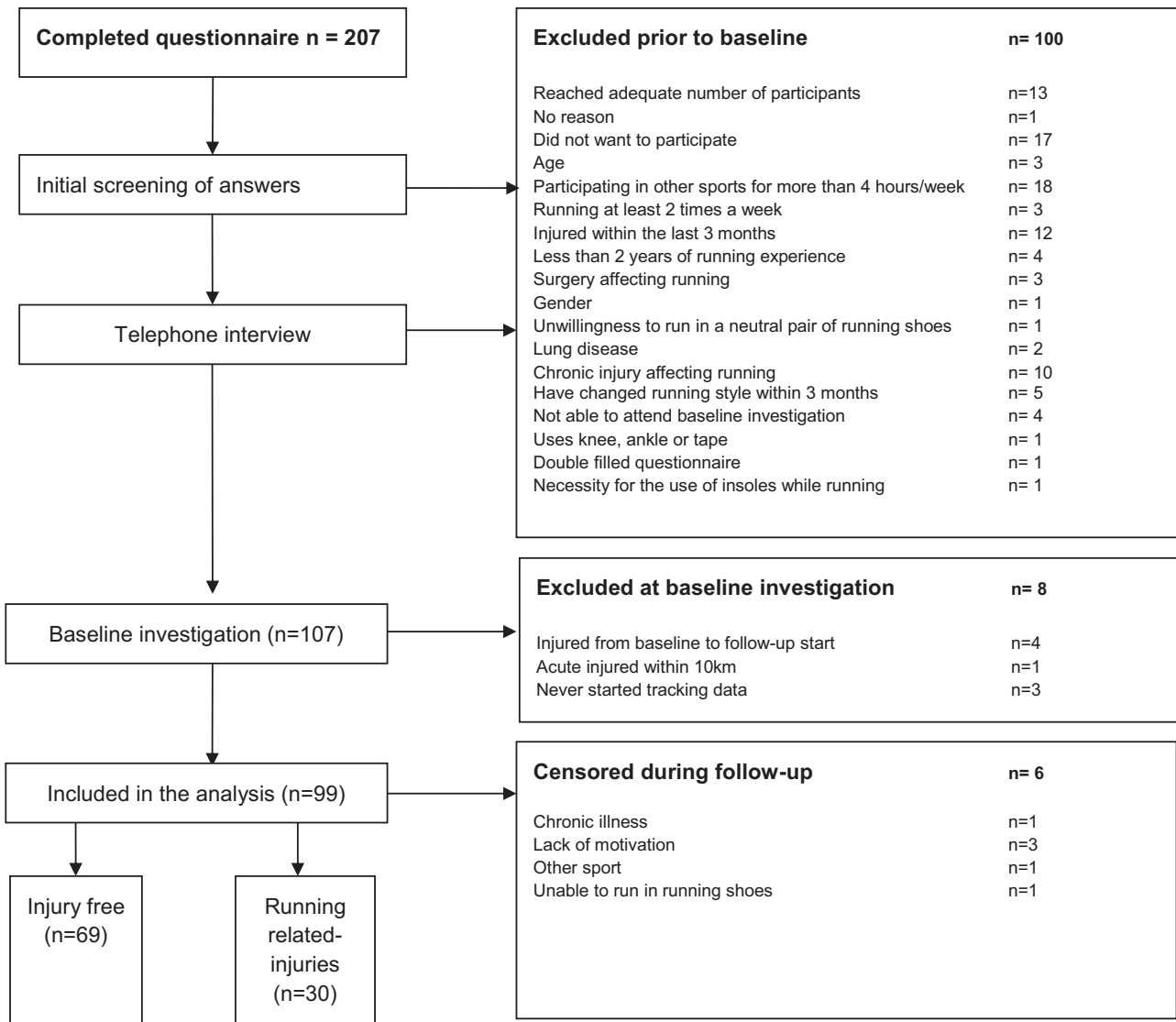


Figure 1. RUNTECH Flow chart with running-related injuries as outcome.

and a 12 mm heel to toe drop) and an armband suitable for their smartphone. Shoes and armband were donated to the runners if they completed 500 km of running within a year in the neutral running shoes and attended a follow-up examination after 500 km of running. Consequently, all runners faced a follow-up period with two possibilities for changing running shoes (1) at baseline and (2) after approximately 500 km. After baseline, all runners had to run 500 km (or until injury) in the prescribed neutral running shoes. During follow-up, runners had to run at least 2 times per week and greater than 10 km in total per week. No restrictions were provided concerning where to run and at which pace. Runners had to quantify running training using smartphones and/or GPS watches to upload it to a web-based diary. If objective data were lost or if it was missing, the runners had to subjectively recall the time

spent running and the distance. Then, they had to upload this subjective information manually, which was considered suitable in absence of GPS-based data (Dideriksen, Soegaard, & Nielsen, 2016). After completing the follow-up examination after approximately 500 km, all runners were allowed to continue running in their preferred running shoe. The 500 km was an approximate as the exact time-slot for the follow-up examination was estimated weekly and scheduled based on running data from the previous 4 weeks. The exact time-slot was calculated by finding the days needed to reach 500 km, which was estimated by dividing the remaining running distance by the average running distance per day the last four weeks. Based on this, a date was scheduled for the follow-up examination, when runners were estimated to reach 500 km within 28 days.

Evaluation of the prescribed shoes

Shoe hardnesses were measured in 24 Asics Gel-pulse5 shoes on the medial and lateral part, using a PCE-DX-A S hardness tester according to the JIS K 7312 protocol for hardness characterization of viscoelastic polymers (Japanese Standards Association, 1996). The average of three hardness values for each shoe size was tested.

Outcome

Running-related injury was defined in accordance with Nielsen et al. (2013): 'A running-related injury was defined as a musculoskeletal complaint of the lower extremity or back caused by running, which restricted the amount of running for at least 1 week'. In order to assess injury status during follow-up, runners received one weekly e-mail with a link to a web-based questionnaire, which addressed the pain status, location and amount consecutive days without running during the week. Runners reporting injuries during the follow-up period were contacted and an appointment for attending a clinical examination, performed by a sports physiotherapist or sports physician, was made. Based on this, all runners with musculoskeletal complaints had their injury classified as either running-related injury, injury from other sport or acute injury.

Data analysis and statistics

This section is structured with respect to the chronology of the analysis. The cumulated running distance was used as the duration scale. In the analyses, cause-specific hazards of the instantaneous risk of injury from a specific injury category (running-related injuries, non-running-related injuries) were calculated using competing risks. Running-related injuries were treated as injuries of interest while non-running-related injuries were treated as competing risk injuries. Only first time injuries were used in the present analysis; however, runners recovering from their injury were still followed for 1-year in total and had to run in the prescribed pair of running shoes. The injury incidence rate as a function of cumulated running distance was estimated using a Poisson regression with restricted cubic spline knots at 50, 100, 500, 600 and 1000 km, which was based on the empirical-based rationale that the influence of changing running shoes was greatest during the first 100 km. Based on the knots, five risk periods were defined: P1 (0–50 km), P2 (50–100 km), P3 (100–500 km), P4 (500–600 km) and P5(600 km–end). The injury incidence rate is plotted after the 5th incidence to increase robustness of the estimated injury incidence rates. The IIRR was calculated as the instantaneous injury incidence rate divided by the average injury incidence rate over the

entire follow-up period. A Wald-test was used to investigate the relative levels of the IIRR curve between risk periods. An exploratory analysis describing the potential differences in training distance between injured and non-injured runners were performed to elaborate on the potential influence of the training distances on the injury risk. The influence of distance per training session as a function of cumulated kilometres in the study assessed using a regression with restricted cubic splines with similar knots as in the primary analysis. Difference in training distance between injured and un-injured runners was evaluated with an unpaired *t*-test. All statistical analyses were performed using Stata Version 15 (StataCorp LP, College Station, TX).

Results

A total of 99 injury-free runners were included in the study (Figure 1). The Asics Gel-pulse5 was categorised as a medium soft running shoe (Shore A values; medial: 42.5 ± 3.35). A total of 30 of the 99 runners sustained at least one running-related injury during the 72.076 km of running with a mean covered distance of 975 (± 790 km) per year. A more detailed description of the injury pattern can be found in Brund et al. (2017). The completion of the follow-up examination at '500 km' corresponding to the time for the optional shoe change occurred on average after 530 km (SD: 51) of running.

Injury incidence rate was overall significantly different between the five risk periods based on the Wald-test (p -value = 0.03). Based on the estimated instantaneous IIRRs from the Poisson regression, the average IIRR during the first 50 km (risk period 1, P1) of running after the first compulsory running shoe change was not clinically relevant different from one (IIRR = 0.98 [95% CI: 0.97; 0.99]; p -value: 0.003). Contrastingly, the average IIRR was above one between 50 and 100 km (1.61 [95% CI: 1.15; 2.24]; p -value: 0.009) (risk period 2, P2) and reduced between 100 and 500 km (0.56 [95% CI: 0.37; 0.84]; p -value: 0.011) (risk period 3, P3). Finally, the average IIRR was insignificantly above one between 500 and 600 km of running (1.47 [95% CI: 0.77; 2.79]; p -value: 0.24) (risk period 4, P4) and insignificantly below one after 600 km of running (0.71 [95% CI: 0.25; 2.02]; p -value: 0.52) (risk period 5, P5).

Graphical presentations of the development of the injury incidence rate and IIRR as a function of kilometres of running are shown in Figure 2(A,B). Figure 2(A) illustrates the instantaneous injury incidence rate and after how many kilometres of running each of the 30 injured runners were covering before they were injured in the follow-up period, whereas Figure 2(B) visualise the modulation of the IIRR. The IIRR-curve indicates that the included runners are at increased risk

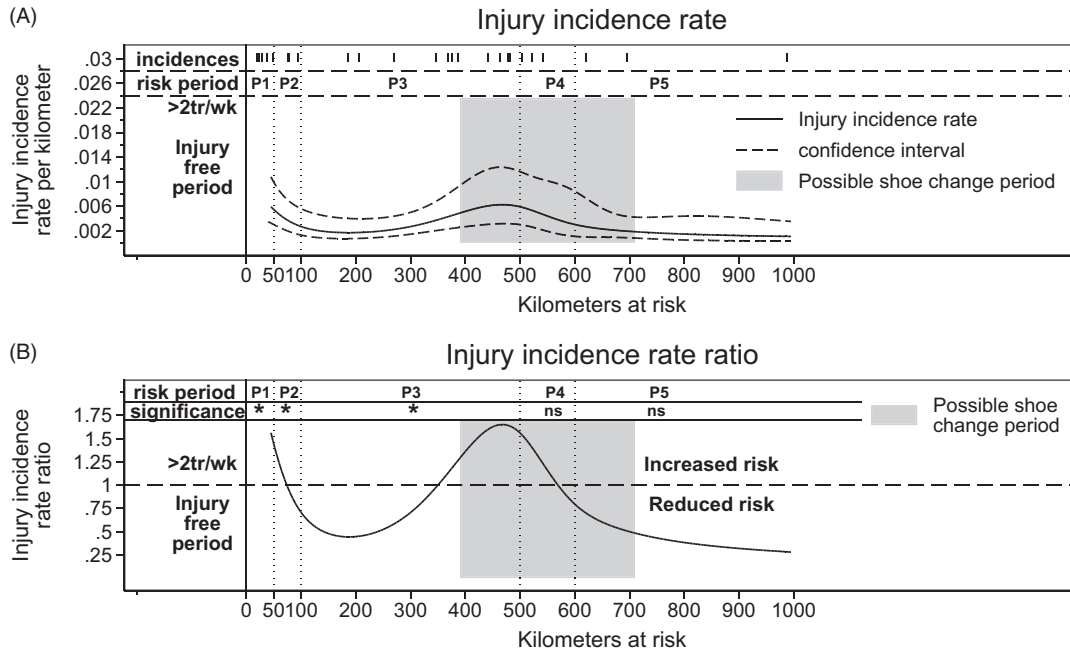


Figure 2. (A) Injury incidence rate across running distance (curves) and after how many kilometres of running each of the 30 injured runners were covered before they were injured in the follow-up period (markings in the top of the figure). The figure contains data from 99 runners changing to the same type of 'neutral' and compulsory running shoe at 0 km and with the possibility to change to optional shoes after a biomechanical assessment at about 500 km of running. Risk periods: P1: first 50 km of the follow-up period; P2: 50 km to 100 km; P3: 100 km to 500 km; P4: 500–600 km; P5: 600 km – end of study. Due to practical issues, the '500 km' examination, in reality, occurred over an interval ranging 385–714 km of running, which is marked with grey on both a and b. The curves illustrating the incidence rate and confidence intervals start after the fifth incidence since these five were used to establish a starting point and thereby to increase robustness of the predicted incidence rate. (B) Predicted injury incidence rate ratio, based on the data illustrated in the panel above. The curve for predicted injury incidence ratio was divided with the average injury incidence rate over the observation period. The horizontal dashed line indicates the average injury incidence level (reference rate = 0.41 injuries per 1000 km of running). Risk periods significantly different from one (p -value < 0.01) is marked with an *. Non-significant results is abbreviated ns. >2 tr/wk is indicating that runners were at least running 2 times per week during the previous 3 months.

from the beginning of the curve (starting after 5 incidences) to around 75 km and between approx. 375 and 575 km of running (Figure 2(B)).

The average self-reported running distance per week before the inclusion in the study for all the included runners was 29.6 km/wk (SD: 20.0). For the group of later uninjured runners ($n = 69$), it was 26.7 km/wk (SD: 17.0); for the later injured runners ($n = 30$), it was 31.7 km/wk (SD: 28.2) which was significantly higher than the former ($p < 0.00001$) (see also Figure 3). The fitted curves of the development of the weekly running distance during the follow-up period are also shown in Figure 3. Overall, the injured runners were running more kilometers per week before the inclusion in the study (p -value < 0.001) and during the first 500 km of running when compared to the uninjured runners (P1: 5.0 km, P2: 12.0 km and P3: 6.5 km greater weekly running distance; p -value < 0.001). The injured runners increased their weekly running distance during the first 100 km of running and from 500 km to 700 km. No statistical differences were found in risk period four and five between injured and un-injured runners. For the un-injured runners, there was a tendency to

that the weekly running distance increased slightly during the first about 600 km, where after the distance began steadily to increase further (Figure 3).

Discussion

The main observations in the present study were (1) the magnitude of the running-related injury incidence rate ratio (IRR) modulated over a one year follow-up period including two running shoe changes, one at the time of inclusion and one after about 500 km of running. The modulation of the IRR demonstrated a significantly elevated level between 50 km and 100 km of running, a significantly decreased level between 100 km and 500 km of running and an insignificant increased level IRR between 500 km and 600 km of running. The elevated IRRs occurred close to the running shoe changes. (2) Based on the present results, it could not be documented that the running shoe changes were the main determinants of the elevated levels of the IRR.

It was hypothesised that due to the change of running shoes the IRR would increase following each

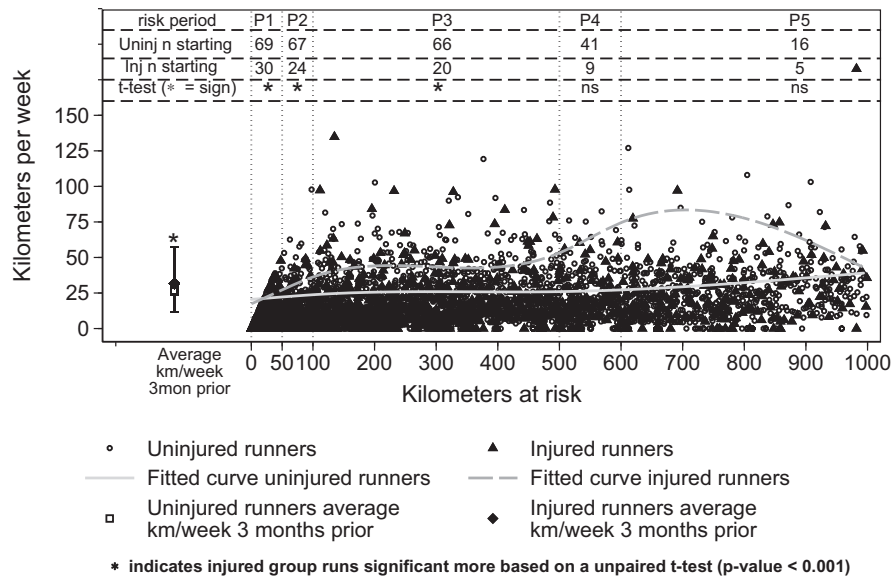


Figure 3. Weekly training distance between runners sustaining an injury and non-injured runners during the follow-up. P1–5: risk periods one to five (see Figure 2); Uninj n starting: number of uninjured runners starting in each risk period; Inj n Starting: number of injured runners starting in each risk period; Unpaired t -test (* = p -value < 0.001).

running shoe change. This hypothesis could not be confirmed. One of the possible reasons for this was that the injured runners on average were progressing more in kilometres per week during both after inclusion and during the first 700 km of running according to the recordings during the follow-up period (Figure 3). This means that the injured runners during the observation period were under increased risk compared to the un-injured runners due to higher increases in running exposure following shoe changes. All the runners should have been under constant injury risk during the observation period apart from the possible added risk imposed by the shoe change if it should have been possible to observe an effect on IIRR of the shoe changes alone. In Figure 3, an increase in kilometres per week for the injured runners was observed after 600 km of running. This increase is based on five runners or below since runners developing injuries were not followed in the analysis in the present study. This may explain why the increase is not significant. However, it can still not be excluded that the development in weekly running distance could have had an influence on the IIRR around the optional shoe change.

It should be noted that a rather large standard deviation was found in the mean covered running distance during the follow-up period, which implies a large difference in running level between runners.

Comparison to other studies and etiological risk of changing shoes

The injury incidence rate, in this study, was reported in Brund et al. (2017) to 0.41 injuries per 1000 km of

running, which is similar to previously reported injury incidence rates amongst recreational runners (Videbaek et al., 2015). Within the body of our knowledge, no other studies have elaborated on the injurious risk of running shoe changes in longitudinal studies. Some studies have proposed or investigated the injurious risk of sudden changes in the mechanics of the running surface. Clement and Taunton (1980) have proposed that changing surface should be carried out gradually. If performed too sudden at the same training volume, the risk of running-related injuries may be increased. This seems reasonable since the change of running surface may change the way the mechanical load is distributed under the foot and in the lower extremity and thereby the lower leg kinematics and/or kinetics (Dixon, Collop, & Batt, 2000; Ferris, Liang, & Farley, 1999; Hardin, van den Bogert, & Hamill, 2004; Stergiou, Bates, & James, 1999). To support this, running on asphalt has been demonstrated to decrease the risk of Achilles tendinopathy (RR: 0.47; 95% CI: 0.25–0.89), whereas running in sand increased the risk for Achilles tendinopathy (RR: 10; 95% CI: 1.12–92.8).

Logan et al. (2010) proposed a gradual change from conventional running shoes to racing flats, to avoid sudden kinetics changes. The effect of changing running shoes has been investigated in two cross-sectional studies comparing injured with controls. Wen et al. (1997) found that injured runners on average changed running shoes every 7th month compared to every 10.8th month for non-injured runners (p -value: 0.016). In support of this, Duffey et al. (2000) found that injured runners were on average changing running shoes after 536 miles,

whereas non-injured runners changed after 693 miles. Assuming that runners in the two above studies were changing running shoes from day to day and kept the same training volume, it is possible that the increased injury risk is owing to the change of running shoes which may be too sudden for the body to adapt to the redistributed mechanical load.

Strengths and concerns

The strengths of the present study were (1) the prospective design following the runners for 1 year, (2) the measure of running distance by GPS and (3) the clinical assessment of running injuries. A limitation of the study is the fact that the first change of running shoes occurred at the inclusion of runners. Because all runners were injury free at inclusion, the injury incidence rate above the average incidence rate of the follow-up period could be explained by (a) the examination at inclusion into the study, (b) change in training patterns immediately after being enrolled in the study, (c) the change of running shoes or (d) various other factors. However, if the pre-conditioning period of an appropriate length was applied, a comparison between the injury incidence rate before and after the shoe change would have been possible, which would have strengthened the study.

Implication of the results

The present results indicate that it cannot be verified that changing running shoes may increase the risk of sustaining injuries briefly after the shoe change, although several uncertainties were present in this study, which leaves open the question on the injurious effects of changing shoes. However, more studies on the topic are needed to elaborate on the magnitude of the change and duration of the possible increased injury risk following shoe change and for example if use of multiple shoes at specific frequency/ies changing the risk of sustaining an injury. Previously multiple shoe users have proven to sustain fewer injuries compared to single shoe users (Malisoux et al., 2015), but the optimal time interval(s) between shoe changes are unknown.

In a future study, a more appropriate design would be a randomised controlled trial starting with a pre-conditioning period where the included runners should run with a standardised running shoe. Thereafter, half of the runners should change to another standardised running shoe and then all the runners should continue running in an intervention period of an appropriate length. The difference in injury risk between the two groups after the intervention period would then give the effect of changing running shoes. Moreover, if feasible, the study should control for running exposure to ensure even

exposure between groups. This design has several advantages compared to the one used in this study. First, all runners will be preconditioned to the same running shoe and running exposure before the second shoe change is known. Second, the most fragile runners will be injured before the intervention and thereby not influence the results.

Conclusion

In the present article, the first step was taken to shed light on the association between changing running shoes and running injury incidence rate. The results revealed increased rates around the time-points at which runners changed running shoes. However, it remains questionable if the increased rates were caused by the changes in shoes or by other factors, e.g., running exposure. Still, there is proposed a plausible theoretical mechanism behind the idea that running shoe change should be a potential injury risk factor, and more large-scale studies are needed to provide further insight concerning the actual strength of this theoretical association.

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