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Review

The Role of Footwear, Foot Orthosis, and Training-Related Strategies in the Prevention of Bone Stress Injuries: A Systematic Review and Meta-Analysis

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ABSTRACT

***International Journal of Exercise Science* 16(3): 721-743, 2023.** Objective: To evaluate the effectiveness of footwear, foot orthoses and training-related strategies to prevent lower extremity bone stress injury (BSI). Design: Systematic review and meta-analysis. Data sources: Four bibliographic databases (from inception until November 2021): Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE and CINAHL. Eligibility criteria: Randomised controlled trials (RCTs) that assessed the risk of developing a BSI when using particular footwear, foot orthoses or training-related strategies such as muscle strengthening, stretching, and mechanical loading exercises. Results: Eleven studies were included in this systematic review. When wearing foot orthoses, the risk ratio of developing a BSI on any lower extremity bone is 0.47 (95% CI 0.26 to 0.87; p = 0.02). When doing pre-exercise dynamic stretching, the risk ratio of suffering a tibial BSI is 1.06 (95% CI 0.67 to 1.68; p = 0.79). No meta-analyses could be performed for footwear or training-related strategies. The quality of evidence for all these results is low considering the high risk of bias in each study, the low number of studies and the low number of cases in each study. Conclusion: This systematic review reveals the lack of high-quality studies in BSI prevention. Based on studies at high risk of bias, foot orthoses could potentially help prevent BSIs in the military setting. It is still unknown whether footwear and training-related strategies have any benefits. It is crucial to further investigate potential BSI prevention strategies in women and athletes. Research is also needed to assess the influence of running shoes and loading management on BSI incidence.

KEY WORDS: Stress fracture, tibia, femur, metatarsal bone, overuse injury, load management, running shoes, runners, infantry, boots

INTRODUCTION

A bone stress injury (BSI) is an overuse injury that can represent a major health problem in athletes and military recruits, especially those involved in long-distance running or any other activities with repetitive loading (8, 27, 28). It consists of a bone injury partially due to a rise in the mechanical stress applied on a bone beyond its adaptive capacity, such as a higher training volume or intensity (8, 67). Such overload can result in an imbalance between bone resorption and bone formation (8, 36, 55).

In the running population, up to 4-5% of high school athletes and 20% of college athletes suffer a BSI every year (34, 68). In the military population, it occurs in 9-10% of female recruits and 3-6% of male recruits (11, 74). Overall, 90% of BSIs occur in the lower extremity, with the tibia and metatarsals being the most frequently affected bones (5, 27, 31, 40, 59, 66).

Potential strategies to prevent BSIs include footwear, foot orthoses (FOs) and shoe inserts, as well as exercise programs, which include modifications of training parameters, muscle strengthening, stretching, and mechanical loading exercises.

A systematic review on BSI prevention with physical interventions was published in 2005 by Rome et al. (61). They suggested that shock-absorbing inserts are probably decreasing the risk of developing BSIs in the military population, but the literature was not robust to draw clear conclusions. According to their review, there was no randomised controlled trial (RCT) assessing the effects of different kinds of running shoes on BSI prevention, and very few RCTs evaluating exercise programs for BSI prevention.

More recently, Bonanno *et al.* (10) reviewed the effect of FOs on musculoskeletal injuries and concluded that FOs can possibly reduce the risk of BSIs. That review, however, did not look at interventions other than FOs.

Over the last two decades, running shoe technologies were significantly modified to improve performance and reduce injury risk (6, 48, 50). Moreover, different stretching modalities have emerged, and dynamic stretching has gained popularity among runners (1, 15, 70). The importance of a progressive mileage increment for injury prevention has also been emphasized in the literature (27). However, it remains unknown if those equipment and training variables influence the risk of developing a BSI.

Thus, this systematic review and meta-analysis aimed to update the literature about the effects of emerging footwear, FOs and training strategies on the prevention of lower extremity BSIs. As opposed to other reviews on that topic, this systematic review aimed to assess the BSI risk of specific bones of the lower extremity since each one has different biological and external risk factors that can potentially be addressed. This systematic review also aimed at identifying research gaps in the field of BSI prevention, as systematic reviews are the gold standard for identifying research gaps and orienting future prospective trials on BSI prevention (51, 60).

METHODS

Participants

This systematic review was conducted under the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (53). In addition, all 27 items of the Prisma in Exercise, Rehabilitation, Sport medicine and SporTs science (PERSiST) guidance were addressed (3). It was registered in the International Prospective Register of Systematic Reviews PROSPERO (CRD42020192210). A protocol for this systematic review was published in 2012 in the Cochrane Library (14).

Criteria for considering studies in this review

The eligible studies were RCTs and quasi-randomized controlled trials (qRCTs) evaluating footwear, FOs, other running equipment and training-related strategies for the prevention of lower extremity BSIs. Trials could include participants of any sex or gender, with regular involvement in occupational (e.g., military) or leisure (e.g. running) physical activities. Any physical intervention aimed at preventing lower extremity BSIs was included. Trials had to compare one or more physical interventions with either no intervention, a placebo intervention or a different intervention. Trials must have recorded BSIs (or stress fractures) as an outcome for inclusion in the review. BSIs (or stress fractures) could be listed as the overall number of BSIs and/or the number specific to a particular bone. There was no restriction on the method of diagnosis of BSIs.

Medial tibial stress syndrome or "shin splints" was considered a separate entity and was not included. Trials testing medication, calcium supplements and other nutritional supplements were also excluded.

Study selection

The electronic search was completed in December 2021 within the following bibliographic databases: the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE and CINAHL, gathering publications from inception until December 1st, 2021. We also searched the WHO International Clinical Trials Registry Platform for ongoing and recently completed trials. No language restrictions were applied. Search strategies for all four databases can be found in Online Appendix 1. A manual search of reference lists of all included articles was performed, in addition to the former Cochrane Review by Rome et al. (61), the systematic review by Bonanno et al. (10), and a related Cochrane review on the prevention of lower extremity soft-tissue injuries by Yeung et al. (75).

Two review authors (AL and DC) independently screened all abstracts, before independently judging eligibility based on full texts. A third review author (BD) was consulted in case of disagreement. When necessary, corresponding authors were contacted to clarify information regarding their study methods, data, and to confirm their eligibility for inclusion.

Data extraction

Two authors (BD and AL) independently extracted information on study characteristics and results: study design, location and year of trial, age of participants, inclusion and exclusion criteria, interventions, number of participants in each intervention group and control group, length of follow up, outcomes, diagnostic method and the number of BSIs in each group. Any disagreement was resolved through discussion. We attempted to contact 14 trial authors for incomplete details on study methods or data.

Assessment of risk of bias in included studies

Two authors (BD and PF) independently assessed each included trial using the first version of the Cochrane Collaboration's Risk of bias tool for assessing the risk of bias in the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias (25). When required, included trials' authors were contacted to clarify unclear methodological details. For each of these seven domains, we assigned a judgment of "high risk" of bias, "low risk" of bias, or "unclear risk" of bias based on the criteria of the Cochrane Handbook (25).

Data analysis

We calculated risk ratios (RR) and 95% confidence intervals (95% CI) since our variable was dichotomous (the occurrence of a BSI), with a fixed-effect model (25). If considered appropriate, results of comparable groups of different trials were pooled. The appropriateness of pooling was determined based on the assessment of clinical heterogeneity in terms of participants, interventions and outcomes of the included studies. The heterogeneity was assessed using the Chi^2 and I^2 values. If substantial heterogeneity was present (e.g., $I^2 = 75\%$) and could not be explained by differences across the trials in terms of clinical or methodological features, the trials were not combined in a meta-analysis, but the results were presented in a forest plot. If heterogeneity was identified, a subgroup analysis was undertaken to investigate possible sources. In addition, a meta-regression was conducted if there were enough studies to assess the effect of the possible sources of heterogeneity. The statistical analysis was performed using RevMan 5.4, which also generated forest plots to allow visual support (13).

Where possible, data were extracted to allow an intention-to-treat analysis in which all randomized participants were analysed in the groups to which they were originally assigned. If there was a discrepancy in the number randomized and the number analyzed in each treatment group, the percentage loss to follow-up was calculated in each group and this information was reported. No assumptions about follow-up losses were made and only results for those who completed the trial were analyzed.

Effects of reporting bias were reduced by a) performing a comprehensive search for published, unpublished and ongoing trials; b) placing no language restrictions on the search strategy; c) checking for multiple trial reports of the same trial; (d) attempting to obtain the protocol or the trial registration documents for trials; and e) contacting the authors in cases where the pre-specified primary outcomes were not reported. All included studies were assessed for adequacy of reporting of data for pre-stated outcomes.

Sensitivity analyses were conducted to investigate the robustness of the results for the primary outcomes by excluding trials at high or unclear risk of selection bias. Sensitivity analyses were also undertaken if trials reported drop-out rates of 10% or greater. If significant heterogeneity was detected and if one or two outlying studies with results that conflicted with the other studies had clinical or methodological characteristics that differed from the other trials, sensitivity analyses with and without these outlying studies were performed.

The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach was used to assess the quality of evidence (22).

RESULTS

Search results

A total of 3798 titles were found using our search strategy, and 23 additional titles were considered based on reference lists of other articles. After full-text reviews, 11 studies were included in this systematic review (2, 9, 16-18, 21, 42, 43, 56, 57). The selection process is illustrated in Figure 1. Both RCTs and qRCTs were included considering the low number of studies available in this field.

Schwellnus *et al.* (62) was excluded because it was not an RCT or qRCT. Also, Simkin *et al.* (64) was excluded because it had redundant data that were originally used by Milgrom *et al.* 1985 (43). All other excluded trials did not measure the effect of footwear, foot orthosis and training-related strategies on the risk of developing BSIs or were not RCTs.

Quality assessment

The risk of bias assessment of the included studies is presented in Online Appendix 2 and illustrated in Figure 2.

Random sequence generation was at low risk of bias for half of the studies. Only two studies were at low risk of bias for the allocation concealment, and two for the attrition bias. Blinding of participants and outcome assessment was at high risk of bias for all studies. The reporting bias was unclear for all studies. Pope *et al.* 2000 *(57)* was the study with the highest number (3) of domains considered at low risk of bias. Nonetheless, all studies included in this systematic review have a high overall risk of bias. Therefore, it was not possible to investigate the robustness of the results for the primary outcomes by excluding trials at high or unclear risk of selection bias.

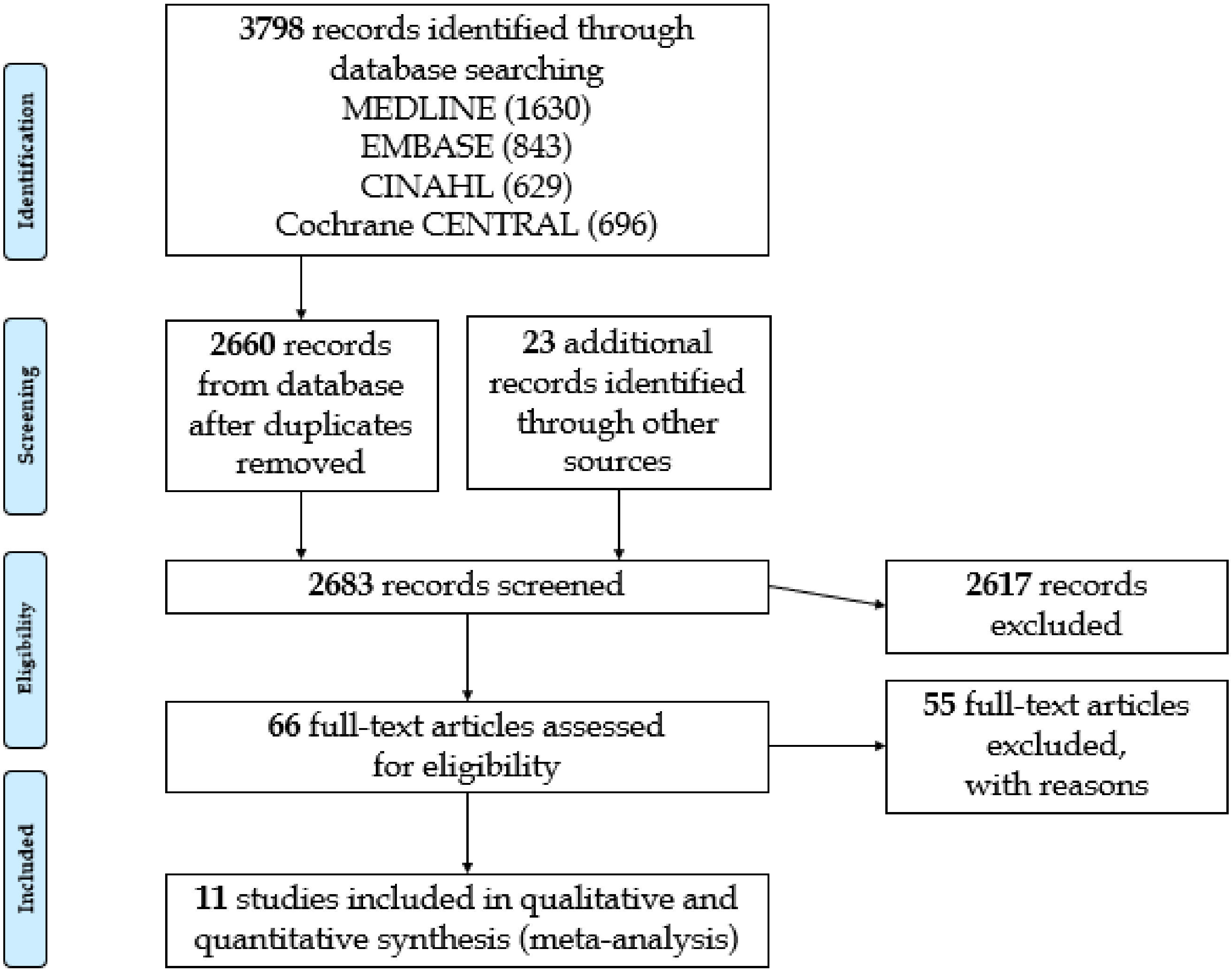


Figure 1. PRISMA diagram of study selection.

Study characteristics

A summary of the study characteristics and results is found in Table 1. Five studies are RCTs and six are qRCTs. They included between 290 and 3025 participants, all military personnel in a training environment, from four countries (Australia, Israel, the United Kingdom and the United States). Franklyn-Miller *et al.* (18) is the only study that included both males and females, whereas all other studies were exclusively composed of males. Andrish *et al. (2)* collected outcomes on both shin splints and BSIs, but only their data on BSIs were considered in this systematic review. The majority of studies did not report the incidence of BSIs over time, but rather the total number of BSIs at the end of their training program. Therefore, when compiling data about the number of participants who suffered a BSI, the denominator was the number of participants in each allocated group who completed their given training program.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Overall risk of bias
Andrish 1974	+	?	-	-	-	?	-	-
Bensel 1976	-	-	-	-	-	-	-	-
Finestone 1999	+	?	-	-	-	?	-	-
Finestone 2004a	+	?	-	-	-	?	-	-
Finestone 2004b	+	?	-	-	-	?	-	-
Franklyn-Miller 2011	+	-	-	-	+	?	-	-
Gardner 1988	-	-	-	-	-	?	-	-
Milgrom 1985	-	-	-	-	-	?	?	-
Milgrom 1992	-	-	-	-	?	?	?	-
Pope 1998	-	+	-	-	?	?	-	-
Pope 2000	-	+	-	-	+	?	+	-

Figure 2. Risk of bias assessment of the included studies. (**+**) low risk of bias; (-) high risk of bias; (**?**) unknown risk of bias.

Types of footwear and FOs

Finestone *et al.* 1999 (16) and Franklyn-Miller *et al.* (18) compared the risk of developing any type of BSI between soldiers wearing FOs versus soldiers who did not wear FOs, and both studies found favorable outcomes with FOs for BSI prevention in general. Four studies, (Andrish *et al.* (2), Finestone *et al.* 1999 (16), Franklyn-Miller *et al.* (18) and Milgrom *et al.* 1985 (43)), also looked more precisely at the incidence of tibial BSIs, and all four studies showed favorable outcomes with FOs for tibial BSI prevention. Additionally, Finestone *et al.* 1999 (16), Franklyn-Miller *et al.* (18) and Milgrom *et al.* 1985 (43) gathered data regarding femoral and metatarsal BSIs separately, and both studies revealed favorable outcomes with FOs for femoral and metatarsal BSI prevention.

The intervention group in Andrish *et al.* (2) used a 1.3 cm thick foam rubber heel pad taped inside tennis shoes for running. In Finestone *et al.* 1999 (16), two kinds of FOs were used for the intervention group: custom-made semi-rigid and custom-made soft FOs. In Franklyn-Miller *et al.* (18), semi-custom 3D FOs were worn by the intervention group. In Milgrom *et al.* 1985 (43), the intervention group was composed of soldiers who wore boots with FOs made of prefabricated semi-rigid polyolefin shells.

Finestone *et al.* 1999 (16), Finestone *et al.* 2004 (17) and Gardner *et al.* (21) compared the effect of different kinds of FOs together (semi-rigid and soft) on the incidence of BSIs. However, the three studies did not compare the same kind of FOs.

More precisely, Finestone *et al.* 1999 (16) used the FOs mentioned above, and Finestone *et al.* 2004 (17) used four different types of FOs: soft custom-made, soft prefabricated, semi-rigid biomechanical and semi-rigid prefabricated FOs. On the other hand, Gardner *et al.* (21) compared polymer insoles with standard mesh insoles.

Footwear was another piece of running equipment studied for the prevention of BSIs. Milgrom *et al.* 1992 (42) studied modified basketball shoes (that were designed exactly like infantry boots) compared with standard infantry boots. Bensel *et al.* (9) compared the use of tropical combat boots with leather combat boots. Neither of those two footwear designs showed a statistically significant difference with regular infantry boots in terms of BSI prevention.

Table 1. Summary of data from the included trials

Author	Design	Participants	Intervention	Control group	Follow-up length	Outcome	Results
Andrish (1974)	RCT	2777 first year midshipmen.	1. A 1.3 cm thick foam rubber heel pad taped inside tennis shoes for running. 2. Stretching exercises of gastrocnemius and soleus for; 3 times per day. 3. Combination of heel pad and stretching exercises. 4. Graduated running program (1/3 of regular running milaege in the first week, 2/3 in the second week, and regular milage from the third week).	Normal physical education program with no additional intervention.	Duration of summer training program.	Tibial stress fractures diagnosed by roentgenograms.	0/344 midshipmen with the heel pad, 1/300 in the stretching group, 0/463 in the heel pad+stretching group, 0/217 in the volume modification group and 1/1453 in the control group had a tibial BSI.
Bensel (1976)	qRCT	990 marine corps recruits.	Tropical combat boots: The leather insole is split into two pieces and a 0.28-cm thick, stainless steel plate is inserted between the pieces and stitched around the periphery for spike protection. The rubber outsole is direct molded to the upper.	Standard leather combat boots.	Twelve weeks of training.	Metatarsal stress fractures. The stress fractures were diagnosed with radiographs.	3/372 recruits with the tropical combat boots and 8/414 recruits with the standard leather combat boots had a metatarsal BSI.
Finestone (1999)	RCT	404 infantry recruits.	1. Custom-made semi-rigid foot orthoses. 2. Custom-made soft biomechanical orthoses.	Simple shoe insoles.	14-week training period.	Stress fractures confirmed with bone scintigraphy.	16/126 recruits in the intervention groups had a BSI (13 tibial and 9 femoral BSIs). 13/53 in the control groups had a BSI (12 tibial, 6 femoral and 1 metatarsal BSIs).

Finestone (2004a)	RCT	451 male infantry recruits.	Soft custom-made orthoses.	Soft prefabricated orthoses.	14-week training period.	Stress fractures (diagnosed by clinical examination only).	19/204 recruits in the intervention group and 19/213 in the control group had a BSI.
Finestone (2004b)	RCT	423 male infantry recruits.	Semirigid biomechanical orthoses.	Semirigid prefabricated orthoses.	14-week training period.	Stress fractures (diagnosed by clinical examination only).	17/180 recruits in the intervention group and 16/172 in the control group had a BSI.
Franklyn-Miller (2011)	RCT	400 male and female new-entry officer cadets.	Semicustomized D3D orthoses.	No intervention.	7-week training period.	Stress fractures (tibial, femoral and metatarsal), confirmed by plain film and magnetic resonance imaging.	2/200 officers in the intervention group had a BSI (1 tibial and 1 metatarsal BSIs). 6/200 officers in the control group (2 tibial, 1 femoral and 3 metatarsal BSIs).
Gardner (1988)	qRCT	3025 United States Marine recruits.	Shock absorbent insoles.	Standard mesh insoles.	12-week training period	Stress fractures confirmed by radiographs.	21/1557 recruits in the intervention group and 17/1468 recruits in the control group had a BSI.
Milgrom, (1985)	qRCT	295 male military recruits.	Military stress orthotics insole.	Boots without orthotic insoles or shoe insert.	14-week training period.	Tibial and metatarsal stress fractures confirmed diagnosed with radiographs or scintigrams.	In the intervention group, 20/113 had a tibial BSI and 2/113 had a metatarsal BSI. In the control group, 35/152 had a tibial and 8/152 had a metatarsal BSI.

Milgrom (1992)	qRCT	390 male Israeli Army recruits.	Modified basketball shoes.	Standard infantry boots.	14-week training period.	Stress fractures confirmed by scintigraphy.	49/187 recruits in the intervention group had a BSI (34 tibial, 22 femoral BSIs). 44/203 recruits in the control group had a BSI (33 tibial, 16 femoral and 7 metatarsal BSIs).
Pope (1998)	qRCT	1093 Australian male Army recruits.	Stretches to the gastrocnemius and soleus muscles before training (2 x 20 seconds static stretches, once every second day).	Stretches to the wrist flexors and triceps muscle (2 x 20 seconds static stretches, once every second day).	12-week training period.	Stress fractures confirmed by bone scan or radiograph.	In the intervention group, 4/451 had a tibial and 4/451 had a metatarsal BSI. In the control group, 8/432 had a tibial and 0/432 had a metatarsal BSI.
Pope (2000)	qRCT	1538 Austalian male Army recruits.	Stretches to gastrocnemius, soleus, hamstrings, quadriceps, hip adductor and hip flexor muscle groups, (1 x 20 seconds static stretches, once every second day, on average) during the warm-up before all physical training sessions.	No stretching exercises.	12-week training period.	Stress fractures (tibia, foot, femur, fibula, Ilium, pubic rami) confirmed by radiographs, CT scan or bone scan.	In the intervention group, 47/623 recruits had a BSI (32 tibial, 11 in the foot, 3 fibular and 1 pubic BSIs). In the control group, 42/562 recruits had a BSI (24 tibial, 10 in the foot, 4 femoral, 1 fibular, 1 iliac and 1 pubic BSIs).

Training-related strategies

Andrish *et al.* (2) studied the effect of stretching exercises and training modifications specifically on tibial BSI incidence. The stretching exercises consisted of stretching the triceps surae for nine repetitions of 15 seconds three times a day. The training modifications involved a more progressive increase in running mileage during the military training camp than what the rest of the soldiers would do. The intervention group ran one-third of the regular mileage on the first week of training and two-thirds on the second week, and then the same training volume as everyone else from the third week and later on. They separately compared the use of a heel pad, triceps surae stretching exercises and training modifications. They also combined wearing heel pads and stretching exercises to measure if it had a different efficacy than wearing heel pads alone or doing the stretching exercises alone to prevent tibial BSIs. Among all those interventions, none had a statistically significant difference in regard to tibial BSI prevention compared with regular military training.

Pope *et al.* 1998 (56) and Pope *et al.* 2000 (57) studied the impact of different kinds of stretching exercises on the incidence of BSIs. In Pope *et al.* 1998 (56), the intervention group stretched their triceps surae while the control group stretched some upper extremity muscles (wrist flexors and triceps brachii, accomplished in two sets of 20 seconds before every session of vigorous physical activity. The intervention group that had been stretching their triceps surae had fewer tibial BSIs and more metatarsal BSIs than the control group. Pope *et al.* 2000 (57) studied the difference between stretching major muscle groups of the lower extremity in one set of 20 seconds for each muscle group (triceps surae, quadriceps, hamstrings, hip flexor and hip abductor muscles) before strenuous physical activity versus no stretching. Individuals who had not been stretching developed fewer tibial BSIs than those who stretched their lower extremity muscles.

Results of meta-analyses

In the fixed-effect meta-analysis comparing the use of orthoses versus no intervention, two RCTs (16, 18) combined 579 participants with 37 cases of BSIs. The risk ratio of developing a BSI on any bone of the lower extremity with the FOs is 0.47 (95% CI 0.26 to 0.87; *p* = 0.02) with negligible heterogeneity, as shown in Figure 3.

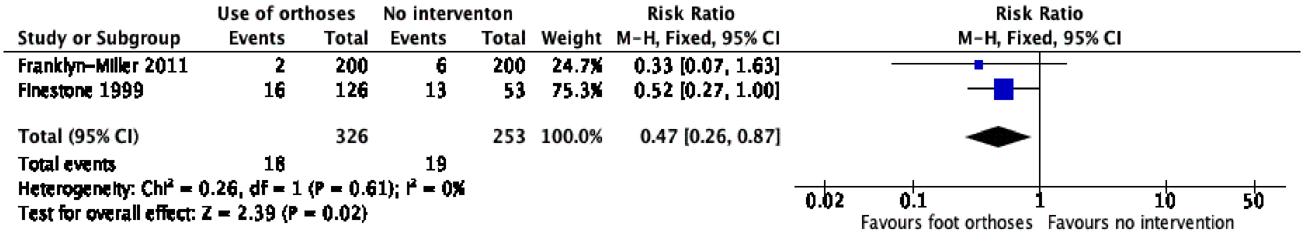
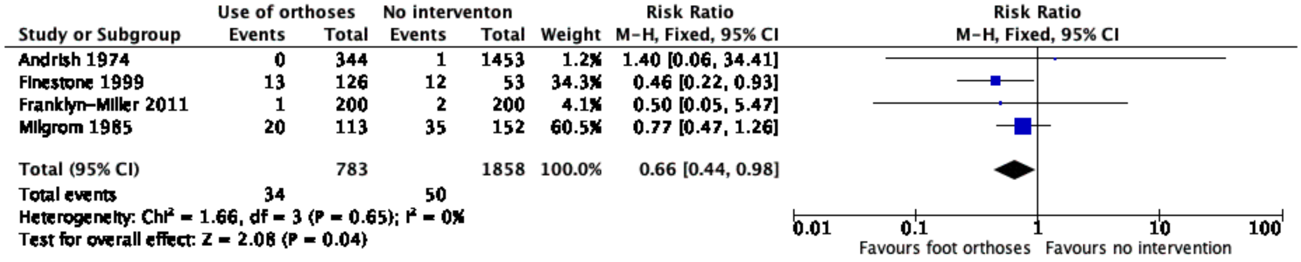


Figure 3: Forest plot comparing FOs versus no intervention to prevent BSIs in general.

Separate meta-analyses with the same comparison (use of FOs versus no intervention) were performed for three common BSI locations separately: tibia, femur and metatarsal bones. The heterogeneity of all subgroups was also negligible. The meta-analysis looking at the tibial BSIs (including four studies, 2641 participants and 84 BSIs) showed a risk ratio of 0.66 (95% CI 0.44 to 0.98; *p* = 0.04) as shown in Figure 4.

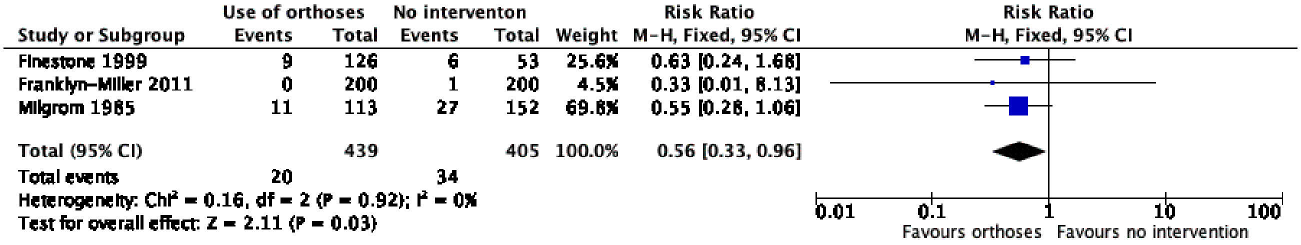


Study or Subgroup	Use of orthoses Events	Use of orthoses Total	No interventon Events	No interventon Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Andrish 1974	0	344	1	1453	1.2%	1.40 [0.06, 34.41]
Finestone 1999	13	126	12	53	34.3%	0.46 [0.22, 0.93]
Franklyn-Miller 2011	1	200	2	200	4.1%	0.50 [0.05, 5.47]
Milgrom 1985	20	113	35	152	60.5%	0.77 [0.47, 1.26]
Total (95% CI)		783		1858	100.0%	0.66 [0.44, 0.98]
Total events	34		50			

Heterogeneity: Chi² = 1.66, df = 3 (P = 0.65); I² = 0%
Test for overall effect: Z = 2.08 (P = 0.04)

Figure 4: Forest plot comparing FOs versus no intervention to prevent tibial BSIs.

The meta-analysis focusing on the femoral BSIs (including three studies, 844 participants and 54 BSIs) indicated a risk ratio of 0.56 (95% CI 0.33 to 0.96; *p* = 0.03) as shown in Figure 5.

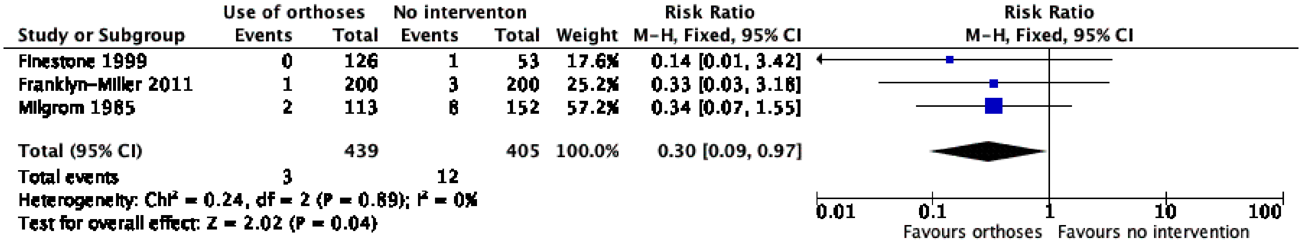


Study or Subgroup	Use of orthoses Events	Use of orthoses Total	No interventon Events	No interventon Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Finestone 1999	9	126	6	53	25.6%	0.63 [0.24, 1.68]
Franklyn-Miller 2011	0	200	1	200	4.5%	0.33 [0.01, 8.13]
Milgrom 1985	11	113	27	152	69.8%	0.55 [0.28, 1.06]
Total (95% CI)		439		405	100.0%	0.56 [0.33, 0.96]
Total events	20		34			

Heterogeneity: Chi² = 0.16, df = 2 (P = 0.92); I² = 0%
Test for overall effect: Z = 2.11 (P = 0.03)

Figure 5. Forest plot comparing FOs versus no intervention to prevent femoral BSIs.

The meta-analysis regarding only the metatarsal BSIs (including three studies, 844 participants and 15 BSIs) yielded a risk ratio of 0.30 (95% CI 0.09 to 0.97; *p* = 0.04) as shown in Figure 6.



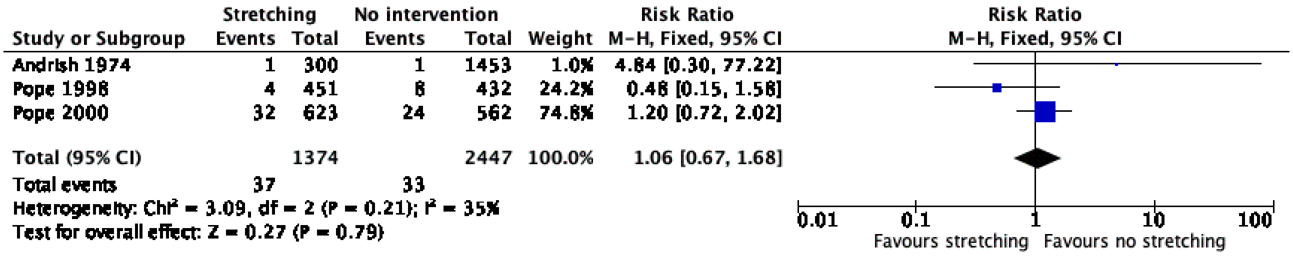
Study or Subgroup	Use of orthoses Events	Use of orthoses Total	No interventon Events	No interventon Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Finestone 1999	0	126	1	53	17.6%	0.14 [0.01, 3.42]
Franklyn-Miller 2011	1	200	3	200	25.2%	0.33 [0.03, 3.18]
Milgrom 1985	2	113	8	152	57.2%	0.34 [0.07, 1.55]
Total (95% CI)		439		405	100.0%	0.30 [0.09, 0.97]
Total events	3		12			

Heterogeneity: Chi² = 0.24, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 2.02 (P = 0.04)

Figure 6. Forest plot comparing FOs versus no intervention to prevent metatarsal BSIs.

For these meta-analyses, the quality of evidence is low according to the GRADE approach considering the high risk of bias in each study, the low number of studies and the low number of cases in each study (22).

Another fixed-effect meta-analysis compared the effect of stretching versus no intervention combining three studies for a total of 3821 participants and 70 BSIs; the risk ratio of suffering a tibial BSI is 1.06 (95% CI 0.67 to 1.68; *p* = 0.79) with negligible heterogeneity, as shown in Figure 7.



Study or Subgroup	Stretching Events	Stretching Total	No intervention Events	No intervention Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Andrish 1974	1	300	1	1453	1.0%	4.84 [0.30, 77.22]
Pope 1998	4	451	8	432	24.2%	0.48 [0.15, 1.58]
Pope 2000	32	623	24	562	74.8%	1.20 [0.72, 2.02]
Total (95% CI)		1374		2447	100.0%	1.06 [0.67, 1.68]
Total events	37		33			

Heterogeneity: $Chi^2 = 3.09$, df = 2 (P = 0.21); $I^2 = 35\%$
Test for overall effect: Z = 0.27 (P = 0.79)

Figure 7. Forest plot comparing dynamic stretching versus no intervention to prevent tibial BSIs.

For this meta-analysis as well, the quality of evidence is low according to the GRADE approach because there were only three studies involved (2, 56, 57), and they each had a high risk of bias and a low number of cases in each study (22).

Results of non-pooled studies

The results of each study included in this systematic review are found in Online Appendix 3. Among the interventions tested for which no meta-analysis could be performed, none of the trials showed a statistically significant difference in the risk of developing a BSI between the intervention and the control groups.

For the FOs, the risk ratio of developing a BSI on any bone is 1.04 (95% CI 0.57 to 1.91; $p = 0.89$) with the soft custom-made orthoses compared to the soft-prefabricated orthoses (Finestone *et al.* 2004a (17)). With the semirigid biomechanical orthoses versus the semirigid prefabricated orthoses, the risk ratio of developing a BSI on any bone is 1.02 (95% CI 0.53 to 1.94; $p = 0.96$) (Finestone *et al.* 2004b (17)).

For footwear comparisons, the risk ratio of suffering a BSI on any bone is 1.21 (95% CI 0.85 to 1.72; $p = 0.30$) with modified basketball shoes compared to standard infantry boots (Milgrom *et al.* 1992 (42)). This trial also looked at the effect of modified basketball shoes on tibial, femoral and metatarsal BSIs specifically, and the difference was not statistically significant in all three subcategories. Another footwear comparison was made between tropical combat boots and standard leather combat boots (Bensel *et al.* (9)), and the risk ratio of developing a metatarsal BSI with the tropical combat boots was 0.83 (95% CI 0.29 to 2.38; $p = 0.74$).

The effect of a training volume modification was studied in only one trial of this systematic review. The risk ratio of suffering a tibial BSI when adapting the training volume with a more progressive mileage increment (Andrish *et al.* (2)) is 2.22 (95% CI 0.07 to 54.40; $p = 0.62$).

DISCUSSION

This This is the first systematic review in 18 years that assessed the risk of developing BSIs with different types of footwear, FOs and training-related strategies. Even though running shoe designs and training strategies have drastically changed in the last two decades (1, 6, 15, 27), very few RCTs on BSI prevention have been published in the meantime. The following discussion highlights the crucial need for prospective trials on running equipment and training strategies and their impact on BSI risk. It also emphasizes the importance of considering the research biases in the current literature on BSI prevention.

Can FOs really prevent BSIs?

First, it is important to understand that all studies about the prevention of BSIs with FOs integrated FOs as a short-term intervention (between 12 and 14 weeks) during a period of intense training like military training camps. Therefore, current evidence does not address the clinical usefulness of wearing FOs in the long term to help prevent BSIs.

The gross statistics in this meta-analysis indicate that FOs in the short-term can possibly reduce the overall risk of developing a BSI in the lower extremity by 53%. Moreover, it indicates that FOs could possibly reduce BSI risk by 70% for the metatarsal bones, by 44% for the femur, and by 34% for the tibia. These numbers seem practice-changing at first sight, but are questionable and need to be nuanced, as the quality of evidence is low.

The meta-analysis by Bonanno *et al.* (10) obtained similar results, with a 58% reduced risk of developing a BSI in the lower extremity while wearing FOs. The results of our meta-analysis and the one by Bonanno *et al.* (10) fit with the hypothesis that FOs can decrease mechanical stress to the metatarsal region (4, 24, 26), which could decrease the risk of metatarsal BSIs during a mechanical overload training period. There is no clear explanation of how FOs influence the tibial and femoral BSI risk, and there is conflicting evidence on whether FOs can modify the loading force applied on the tibia and the femur during running (32, 35, 37, 65). Another meta-analysis by Paradise *et al.* (54) analysed the impact of FOs on lower extremity overuse injuries in general and found no significant difference in the risk of sustaining a lower extremity injury when wearing FOs, but they did not specifically address their effect on BSIs.

Severe limitations could have influenced our results. It is extremely hard to blind both the participants and the staff in non-pharmacological studies, which none of the studies did in this systematic review. Also, most studies in the meta-analyses had no intervention for the control group, which could lead to a placebo effect in the FO group. Furthermore, none of the studies perfectly blinded the outcome assessment. It should also be noted that in Andrish *et al.* (2), the control group was partially made of clusters that did not respect their given assignment, which altered the random effect. Therefore, the results of our meta-analysis must be interpreted cautiously since the only four studies (Andrish *et al.* (2), Finestone *et al.* 1999 (16), Franklyn-Miller *et al.* (18), Milgrom *et al.* 1985 (43)) that investigated the impact of FOs on BSIs had severe limitations.

In order to better appreciate the clinical impact of FOs, it would be important to measure the biomechanical effects (e.g. changes in plantar pressure) of FOs used in the different BSI studies. It must be noted that, even if sham FOs are used as a control group intervention, it would be crucial to consider that even sham FOs may influence plantar pressures, and potentially injuries (41).

Another concern is that studies in the meta-analysis gathered data from training programs of different lengths. Therefore, the number of cases of BSIs in the intervention groups and the control groups was determined among the participants that completed a given training program, regardless of its duration, potentially leading to an experimental mortality bias.

Does one type of FO stand out?

When comparing the risk of developing a BSI with different types of FOs, none of the three studies (Finestone *et al.* 2004a and 2004b (17) and Gardner *et al.* (21)) found a statistically significant difference. It is important to note that Finestone *et al.* 2004a and 2004b (17) were also the only two trials in this systematic review that did not use any imaging modalities to diagnose BSIs, but only a clinical evaluation, which could have decreased precision in their results. Another systematic review on BSI prevention by Rome *et al.* (61) also concluded there was no statistically significant difference between different types of FOs for BSI prevention. As FOs' mechanism to prevent BSIs is unclear (23), it is not possible to assume that FOs with particular features prevent BSIs more than others. It is possible that some types of FOs are better suited for precise foot morphologies (49, 63), thus it seems more relevant to consider some foot characteristics than BSI prevention properties when choosing an FO.

Footwear and BSIs

Army boots and basketball shoes that look like army boots were the only footwear studied in the included trials of this systematic review (Bensel *et al.* (9) and Milgrom *et al.* 1992 (42)). None of those types of footwear had any preventive effect on the incidence of BSIs, according to these two studies that are again at high risk of bias.

Research is warranted to clarify if a specific shoe design can prevent BSIs more than others, as no RCT has yet compared the effect of different types of shoes on BSIs specifically. Certain shoe features have been evaluated for the prevention of lower extremity injuries in general, such as cushioning, motion control system and shoe arch height, but their effect on BSIs prevention is unknown (33, 38, 39). A Cochrane Review has recently assessed the effect of different types of footwear on the prevention of running injuries in general and has also reached similar conclusions about the unknown effect of footwear considering the limitations of their included studies (58). Moreover, multiple studies have evaluated the impact of carbon-plated shoes on running economy and performance since they have been very popular in the worldwide running community within the last few years, but their influence on the risk of suffering a BSI or any other soft tissue injuries, compared to other types of running shoes is also unknown (6, 48, 50).

Stretching and BSIs

This meta-analysis yielded no significant difference in developing BSIs when performing static stretching versus no stretching before physical activity, but once again, the quality of evidence is low.

According to two other systematic reviews (Thacker *et al.* (69) and Behm *et al.* (7)), it appears that pre-activity static stretching has no clear effect on the overall incidence of injuries. Stretching can increase joint range of motion (1), but no study has yet confirmed whether increased or decreased flexibility modulates BSI risk (8).

No RCT has yet assessed the occurrence of BSI when performing pre-exercising dynamic stretching.

Load management and BSIs

Even though some evidence suggests that a slow progression of mileage and intensity in a running program can limit the risk of suffering a BSI (30, 71, 72), the only trial in this systematic review studying the effect of training volume modification did not go along this theory (Andrish *et al.* (2)), as the difference between the two groups was not statistically significant. The mileage increment used in the methodology of this trial seemed arbitrary, as they ran 33% of the regular mileage during the first week of training, 66% on the second week, and 100% on the third week and later on. Some expert clinicians recommend a much slower progression to give bones enough time to adapt, although science does not conclude on optimal workout volume progression (20). As described by Wolff's law, form follows function, and bones may behave in a similar way as they adapt to stresses progressively applied to their structure, but it takes time (12, 47, 52).

Strengths and limitations of this systematic review

This systematic review has a robust methodology that follows all the PRISMA and PERSiST guidelines. The inclusion and exclusion criteria were applied rigorously, and the design of each trial was analyzed in depth to make sure only RCTs or qRCTs were included. Although this systematic review presents a list of RCTs that is quite similar to the one by Rome *et al.* (61), the RCTs are criticized in accordance with updated literature such as biomechanical and clinical studies published in the last decade.

In addition, instead of assessing the risk of developing BSI in general as previously done in other reviews, this systematic review uniquely evaluates preventive measures for BSI of specific bones. It is important to consider each type of BSI separately when assessing the preventive role of running equipment and training strategies since runners do not have the same risk of developing each type of BSI (19). Indeed, biomechanical and external risk factors have been specifically identified for tibial, femoral and metatarsal BSI (29, 45, 46, 73).

Participants recruited in the trials of this systematic review do not represent the general population for numerous reasons. Firstly, all the trials were done with soldiers. It is unknown if athletes and the general population respond the same way as soldiers to physical interventions influencing the risk of BSI. Secondly, there is only one study (Franklyn-Miller *et al.* (18)) among the 11 RCTs that included female participants. The studies were performed in military settings where soldiers were heavily represented by men. Thirdly, most studies excluded soldiers who had a pre-existing lower extremity injury. These soldiers did not necessarily have the same risk of suffering a BSI, especially if their pre-existing injury was a BSI itself (27).

Medial tibial stress syndromes were excluded from this systematic review to focus solely on BSIs, even though these two tibial pain diagnoses share common characteristics.(44) The only trial in which BSIs were diagnosed without imaging (Finestone *et al.* 2004 (17)) could have misdiagnosed BSIs that were actually medial tibial stress syndromes, or vice-versa. This could have influenced the effects of BSI preventive strategies, and the results from this review.

Our comprehensive analysis of the risk of bias performed according to the Cochrane Handbook criteria revealed that all 11 studies included in this systematic review were at high risk of bias in at least three of the seven categories of bias.

Future Directions

In new research on BSI prevention, it is crucial to include more women participants and to include both military recruits and athletes. Creative ways to blind participants and research staff on the presence of FOs and the type of footwear should be implemented in studies on BSI prevention, as already done in other running injury studies (39). Precautions to blind outcome assessment could be taken as well. Interventions that need to be further assessed to better understand their influence on the BSI risk included but are not limited to different types of running shoes such as minimalist or maximalist shoes, motion control shoes, carbon-plated shoes, different types of FOs and different running mileage increments. Longer-term follow ups are necessary to determine any preventive effects of FOs. Furthermore, studies on BSI prevention could all follow their participants within the same time frame, monitor the participants' running mileage and diagnose BSIs exclusively with magnetic resonance imaging.

Conclusion

The use of FOs may or may not decrease the risk of suffering BSIs in a population of soldiers. The results of our meta-analyses have a low quality of evidence on the GRADE scale and they need to be interpreted diligently because of the limited number of studies and the high risk of bias in each study. This robust review enlights the sports medicine community that to this day, there is still a lack of evidence regarding BSI prevention with footwear, FOs and training-related strategies. More studies are needed to understand the impact of footwear, FOs, stretching and load management on BSIs, especially in women and athletes.

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