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REVIEW ARTICLE

Does Shoe Insole Modification Prevent Stress Fractures? A Systematic Review

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Abstract Stress fractures can be debilitating in athletes and military personnel. Insoles may lower stress fracture rates by improving biomechanics, lessening fatigue, and attenuating impact. The objective of this study was to systematically review the best evidence on the use of insoles as a method of stress fracture prevention in a high-risk population. Using MEDLINE, Cochrane, Current Controlled Trials, UK National Research Register, Science-Direct, CINAHL, and EMBASE, a review of randomized (level I) and quasi-randomized (level II) controlled trials was performed using an insole as the intervention and stress fracture incidence as the primary outcome measure. Five trials were included, and a random effects model was used to generate a summary estimate and an overall odds ratio. One study found a significant reduction in overall stress fracture incidence using a semirigid insole, while four studies found no overall reduction in military personnel. However, when the data are pooled, orthotic use was beneficial. When stratified by site, there was a reduction in femoral and tibial stress fracture incidence. Shoe insoles may reduce the overall femoral and tibial stress fracture incidence during military training. It is unclear if the use of insoles would prevent stress fractures in athletes. Additional studies are necessary to determine the efficacy of insoles in an athletic population.

Keywords insoles · stress fracture · prevention

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Introduction

Stress fractures can be debilitating injuries that negatively impact both competitive athletes and active military personnel. The overall incidence of stress fractures among National Collegiate Athletic Association athletes is 1.0–2.6%, and, in the military, stress fractures affect 1.0–1.7% of the soldiers [1–7]. Stress fractures can occur in a variety of anatomic locations and with varying frequency. In the lower extremity, femoral, tibial, and metatarsal stress fractures are most common. In a review of 370 athletes with stress fractures, the tibia was the most commonly involved bone (49.1% of cases), followed by the tarsals (25.3%) and the metatarsals (8.8%) [8]. Bilateral stress fractures occurred in 16.6% of cases. Current prevention strategies include calcium supplementation, participation in a graduated training or running program prior to the onset of military training or athletic participation, cyclical rather than progressive training strategies, introduction of a rest period after the onset of physical training, and improved shock attenuation of the foot, via either shoe modification or use of an insole [9–13].

Shoe inserts, or orthotics, are available in a variety of preparations and can be constructed from many different materials depending on their function and the desired rigidity or support. Similarly, both generic (over-the-counter or off-the-shelf) and custom-molded (prescription) preparations can be used. The size of these insoles ranges from a simple heel cup to a full-length insert that extends to support the forefoot and toes. A variety of devices accommodate for any number of different foot types or limb alignments and can be constructed with individualized posting or recesses to address specific pathology. In this

Table 1 Level of evidence grading in orthopedic literature, adapted from Smith et al. [16]

Preventative studies	
Investigating the results of an intervention	
Level I	RCT Significant difference No significant difference Systematic review of level I RCTs (studies were homogenous)
Level II	Prospective cohort study Poor-quality RCT (e.g., <80% follow-up) Systematic review Level II studies Nonhomogenous level I studies
Level III	Case-control study Retrospective cohort study Systematic review of level III studies
Level IV	Case series (no, or historical, control group)
Level V	Expert opinion

RCT randomized controlled trial

way, all foot types, from planovalgus to cavovarus, can be fitted with an appropriate accommodative orthotic insert.

Previous studies have investigation whether insoles lower stress fracture incidence by improving foot biomechanics, lessening fatigue of the lower extremities, and attenuating impact better than a conventional military boot or training shoe [14–16]. Because the military boot is designed to protect the foot from blunt trauma and to protect the ankle from inversion injury, the standard boot is particularly amenable to the insertion of insoles to prevent lower extremity stress fractures in military recruits. However, despite considerable interest, this belief has not been uniformly supported. At the same time, no systematic review or meta-analysis has made use of the considerable body of evidence on this topic to critically assess the role of insoles in stress fracture prevention.

For this reason, a systematic review was performed to evaluate the best evidence (levels I and II studies) on the use of shock-absorbent insoles as a method of stress fracture prevention in a high-risk population. The objective of this review was to determine the effect of insole use on the overall and site-specific incidence of stress fractures.

Materials and methods

To identify relevant publications on the use of shock-absorbent insoles for the prevention of stress fractures, an exhaustive review of the English-language literature was conducted using MEDLINE (January 1966 through November 2007), Cochrane databases, Current Controlled Trials (http://www.controlled-trials.com), UK National Research Register (http://www.update-software.com/national), ScienceDirect, CINAHL, and EMBASE. Initially, the search was restricted to randomized controlled (level I) trials. The results of this search were limited, however, and the search was expanded to include quasi-randomized controlled (level II) studies evidence as well [17] (Table 1).

Using the search term "stress fracture" (without quotation marks) with the limit "English language", articles were retrieved from MEDLINE. The same search terms with the addition of the term "prevention" were used to search

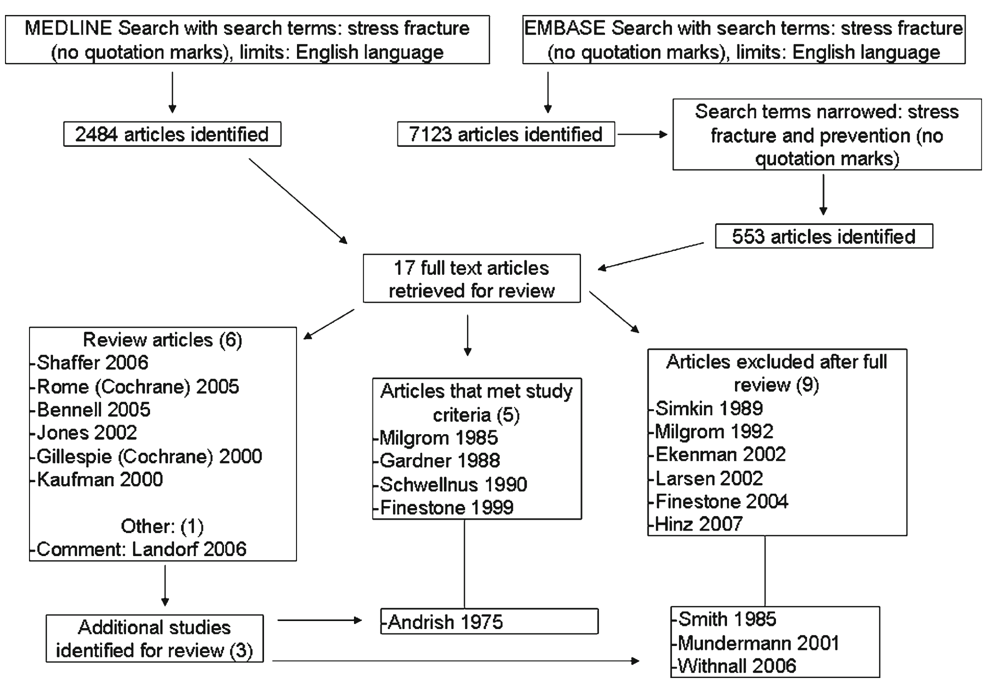

Fig. 1. The literature search and flow of articles—articles reviewed from MEDLINE and EMBASE were excluded based on title or abstract and adding the term "prevention" (EMBASE). Of the resulting 17 manuscripts, six reviews and one "Comment" paper were eliminated. Five of the remaining ten studies met the inclusion criteria [14, 24, 26–28]. Two authors used the same data, but only one (Milgrom et al.) was included in the review [24, 28]. One additional study was identified resulting in five total trials included in this review [9]

EMBASE. From these two searches, 17 original full-text manuscripts were identified. No additional studies were identified through similar searches of the other scientific databases. The inclusion criteria for the review were (1) level I or II evidence, (2) use a shock-absorbent insole as the intervention, and (3) incidence of lower extremity stress fractures as the primary outcome measure. Each of the 17 articles was reviewed independently by two authors using a published worksheet adapted from evidence-based guidelines [18]. The search processes and trial flow are summarized in Fig. 1, while information regarding exclusion of specific articles is presented in "Appendix" [10, 15, 16, 19–25].

From the literature review, five trials met the inclusion criteria: three level I and two level II studies [17]. Data for each of the studies were collected and were presented in Table 2. Subjects are male active duty military personnel serving in the Army, Naval Academy, and Marines. Age was generally consistent in the five studies, with a range of 18.5–20.0 years [14, 26, 27]. The median duration of follow-up was 13 weeks in the four studies that included this information. The study of Gardner et al. was the only study to report race [26, 27]. The material composition of the shock-absorbent insoles in each study varied significantly from custom made orthoses to commercially available neoprene insoles, and little information was provided regarding the rationale for particular insole selection.

To evaluate the effect of insoles use on stress fracture prevention, we performed an analysis of overall stress fracture incidence. Stress fracture incidence was defined as the total number of stress fractures divided by the total number of subjects per group at the beginning of the study. In order to account for study variation (heterogeneity), a random effects model was developed using Review Manager 5.0 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008). This model was used to generate a summary estimate and to calculate an overall odds ratio (OR) using the method of DerSimonian–Laird.

One study only reported the overall incidence of tibial stress fractures [9]. Because the methodology was unclear, whether or not they evaluated their subjects for fractures at other locations is unknown. For this reason, the data from this study were included only in the tibia subgroup analysis [14].

Results

In this systematic review, only one of the five studies reviewed found a statistically significant reduction in overall stress fracture incidence following the introduction of an insole. In this study, subjects were allocated to three groups: a custom-made semirigid insole, a custom-made soft insole, or a control group. The authors reported a 14% reduction in overall stress fracture incidence (p=0.013) when the use of a custom-made semirigid insole was compared to control [14]. The other four studies reviewed found no reduction in overall stress fracture incidence in military personnel using insoles compared to controls [9, 26–28].

While the study by Milgrom et al. did not find a reduction in the overall incidence of stress fractures, a

Table 2 Details of studies included in systematic review

Authors	Study design	Intervention	Population and country	Mean age (range)	Period of evaluation (weeks)	Follow-up	Blinded assessment	Method of diagnosis	Level of evidence
Andrish et al. [9]	RCT	Heel pad	Naval academy first year midshipmen, USA	NR	NR	1,797/1,797 (100%)	NR	XR	I
Milgrom et al. [28]	RCT	Urethane insole	Infantry recruits, Israel	NR	14	265/312 (84.94%)	NR	XR/Bone scan	I
Gardner et al. [26]	QRCT	Viscoelastic polymer	Marines, USA	20.0 (18–41)	12	3,025/3,025 (100%)	Yes[a]	Clinical evaluation/XR	II
Schwellnus et al. [27]	RCT	Neoprene insole	Military recruits, South Africa	18.5 (17–25)	9	1,388/1,511 (91.86%)	NR	XR	I
Finestone et al. [14]	RCT	Custom polypropylene semirigid insoles and polyurethane soft insoles	Infantry recruits, Israel	18.8 (17–27)	14	197/404 (48.76%)	NR	Bone scan	II

RCT randomized controlled trial, *QRCT* quasi-randomized controlled trial, *NR* not reported, *XR* X-ray

[a] Two radiologists independently evaluated radiographs of injured recruits. Both radiologists were blinded with respect to insole status, and the second reviewer was blinded concerning the primary evaluation [25]

Study or Subgroup	Intervention Events	Intervention Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Andrish 1974	0	344	1	1453	3.5%	1.41 [0.06, 34.57]	1974
Milgrom 1985	33	143	70	152	33.1%	0.35 [0.21, 0.58]	1985
Gardner 1988	21	1557	17	1468	29.1%	1.17 [0.61, 2.22]	1988
Schwellnus 1990	0	250	14	1261	4.4%	0.17 [0.01, 2.89]	1990
Finestone 1999	22	260	25	144	29.9%	0.44 [0.24, 0.81]	1999
Total (95% CI)		**2554**		**4478**	**100.0%**	**0.54 [0.29, 1.01]**	
Total events	76		127				

Heterogeneity: $Tau^2 = 0.24$; $Chi^2 = 9.64$, df = 4 (P = 0.05); $I^2 = 59\%$
Test for overall effect: Z = 1.93 (P = 0.05)

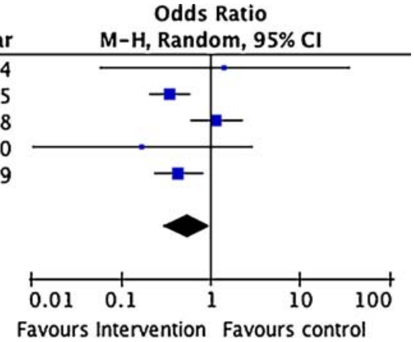

Fig. 2. Overall incidence of stress fractures—a forest plot representation of the pooled data from the five included studies demonstrates a beneficial trend in favor of the use of an orthosis

significant reduction ($p<0.05$) in the incidence of femoral stress fractures was present in their subgroup analysis [28]. This benefit did not, however, result in a reduction in the number of tibial or metatarsal stress fractures.

When the data from the five-included studies were pooled for analysis, a beneficial trend in favor of the use of an orthosis was identified. These data, comparing the use of an insole to control, have an OR of 0.54 (95% confidence interval (CI) 0.29–1.01; Fig. 2).

When the data set is stratified by anatomic location, there is a more significant reduction in the incidence of femoral (OR=0.44, 95% CI 0.25–0.78) and tibial (OR=0.52, 95% CI 0.33–0.83) stress fractures with the use of insoles (Figs. 3 and 4). For metatarsal stress fractures, the trend suggests that insoles prevent stress fractures, but it is not conclusive (OR=0.29, 95% CI 0.08–1.05; Fig. 5).

In considering the variation in the type of insole used in the individual studies, a separate analysis of the data was performed excluding the trial by Andrish et al. This investigation enrolled some 1,797 participants and made use of a heel cup, rather than a full-length insole. This separate effort to control for the potential confounding effect of this one study revealed an overall OR of 0.52 (95% CI 0.27–1.01). The site-specific analysis of the pooled data without this larger study yielded a femoral OR of 0.42 (95% CI 0.24–0.75), a tibial OR of 0.51 (95% CI 0.32–0.82), and a metatarsal OR of 0.29 (95% CI 0.08–1.05).

Additionally, as part of the systematic review, each study was evaluated for potential sources of bias. The trial by Gardner et al. is limited in its generalizability due to a selection bias. In this study, a quasi-random allocation structure was used; the participants' intervention was assigned by platoon number [26]. Similarly, for this review, the method of diagnosis for the stress fracture is central to the quality of investigation. The use of different diagnostic methods by separate studies may influence the number of stress fractures detected in each trial. Consequently, this disparity may introduce a detection bias to the systematic review. Both Andrish et al. and Schwellnus et al. used plain radiographs to diagnose stress fractures, while Finestone et al. used a bone scan [9, 14, 27]. Bone scans can detect stress fractures at an earlier stage than radiographs; thus, a study utilizing bone scans will likely detect a higher incidence of stress fractures than one utilizing only plain radiographs [14, 28]. Ideally, each study would have blinded the radiologist and diagnosing physician to the subjects' assigned group to prevent any observer bias. Only Gardner et al. reported blinding of the radiologists or clinicians to the participants' assigned group [26].

Generally, to limit the effect of an exclusion bias, the preferred percentage of follow-up for a level I study is 80% [17, 29]. In this series, one study did not meet this criterion, provided follow-up on less than 50% of participants, and, therefore, may be affected by exclusion bias [14].

Each of the five studies provided limited information on the method of statistical analysis. A sample size calculation for a given power was not reported in any of the studies. Milgrom et al. reported that the average number of stress fractures per recruit in the insole and noninsole groups was the same, concluding that insoles did not affect overall stress fracture incidence. In a subgroup analysis, however, this study also reported that the use of insoles resulted in a significant reduction in femoral stress fracture incidence. After contacting the authors of this study, the data regarding the total number of recruits with stress fractures in each group were requested. Unfortunately, this information was not provided.

Study or Subgroup	Intervention Events	Intervention Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Milgrom 1985	11	143	27	152	58.9%	0.39 [0.18, 0.81]	1985
Schwellnus 1990	0	250	1	1261	3.2%	1.68 [0.07, 41.29]	1990
Finestone 1999	9	260	10	144	38.0%	0.48 [0.19, 1.21]	1999
Total (95% CI)		**653**		**1557**	**100.0%**	**0.44 [0.25, 0.78]**	
Total events	20		38				

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.83$, df = 2 (P = 0.66); $I^2 = 0\%$
Test for overall effect: Z = 2.83 (P = 0.005)

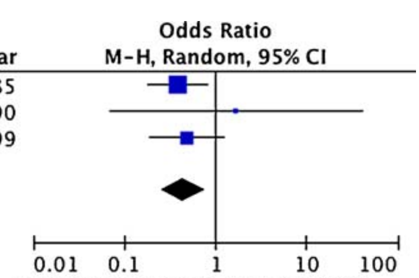

Fig. 3. Incidence of femoral stress fractures—the incidence of femoral stress fractures significantly reduced with the use of insoles

Study or Subgroup	Intervention Events	Intervention Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Andrish 1974	0	344	1	1453	2.1%	1.41 [0.06, 34.57]	1974
Milgrom 1985	20	143	35	152	59.7%	0.54 [0.30, 1.00]	1985
Schwellnus 1990	0	250	10	1261	2.7%	0.24 [0.01, 4.07]	1990
Finestone 1999	13	260	14	144	35.5%	0.49 [0.22, 1.07]	1999
Total (95% CI)		**997**		**3010**	**100.0%**	**0.52 [0.33, 0.83]**	
Total events	33		60				

Heterogeneity: Tau² = 0.00; Chi² = 0.71, df = 3 (P = 0.87); I² = 0%
Test for overall effect: Z = 2.72 (P = 0.006)

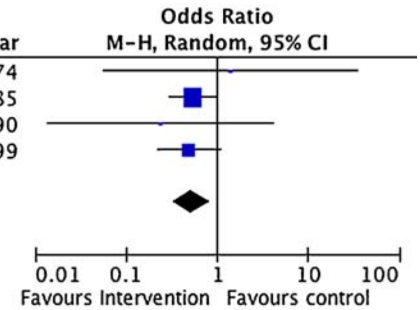

Fig. 4. Incidence of tibia stress fractures—in this forest plot, the use of insoles has significantly reduced the incidence of tibia stress fractures

In order to avoid undermining the randomization process, it is important that studies use an intent-to-treat analysis. With this type of evaluation, the outcomes of patients who did not finish the study, or who changed groups during the study, are reviewed according to their original group assignment. None of the five studies in this review present the results of an intent-to-treat analysis. While the study by Gardner et al. would not qualify as they experienced no withdrawals or crossover, both Milgrom et al. and Schwellnus et al. excluded the outcomes of subjects who withdrew from the study in their analysis [26–28]. While Andrish et al. and Finestone et al. did not exclude withdrawals, they also did not perform an intent-to-treat analysis for those participants that deviated from their group assignment [9, 14].

Discussion

Stress fractures are overuse injuries that result from repetitive activity and occur most often in athletes and military personnel. In this systematic review, we evaluated the best evidence available to determine the effect of insole use on the overall and site-specific incidence of stress fractures in a high-risk population. When considered individually, only one of the five studies that meet the inclusion criteria found a significant reduction in overall stress fracture incidence using a semirigid insole [14]. Similarly, only the study by Milgrom et al. identified a significant site-specific reduction in the incidence of stress fractures within their femoral subgroup analysis [28]. However, drawing on the power of a systematic review, when the data from all five studies were pooled, a trend in favor of orthotic use was identified. This benefit included a reduction in the overall incidence of stress fractures (OR=0.54) as well as a more significant site-specific reduction in the incidence of femoral (OR=0.44) and tibial (OR=0.52) stress fractures.

Considering the quality of the pooled data, it is important to acknowledge that the quantity and quality of physical activity of the study participants is paramount to the stress fracture incidence. In this way, to accurately compare separate groups in different studies, injury exposure may be calculated to normalize an individual's risk by recording the total number of training hours or it can be expressed as training per unit of time. However, even this measure does not account for all characteristics of the exposure, such as the intensity. Gardner et al. reported that recruits underwent 92 h of physical training and 41.5 h of drill or ceremony over the 12-week course, while Schwellnus et al. reported that insole and control groups underwent "identical training" throughout the study [26, 27]. None of the remaining studies provided information regarding time or intensity of physical training, and, as a result, the incidence of stress fractures is not corrected per unit exposure.

Each study reported the cumulative incidence of stress fractures, or the incidence of injury, is calculated over a specific time period in which all individuals are at risk [30]. Because the five studies evaluated military trainees over varying lengths of time (9 to 14 weeks), studies with a longer duration are more likely to report a higher number of stress fractures.

Additionally, the effective sample size for each study is determined by how many outcomes of interest are observed, i.e., stress fractures. Given the small number of stress fractures in these studies, the statistical power to detect significant differences among treatment groups is limited.

Study or Subgroup	Intervention Events	Intervention Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Milgrom 1985	2	143	8	152	65.9%	0.26 [0.05, 1.22]	1985
Schwellnus 1990	0	250	3	1261	18.4%	0.72 [0.04, 13.94]	1990
Finestone 1999	0	260	1	144	15.7%	0.18 [0.01, 4.54]	1999
Total (95% CI)		**653**		**1557**	**100.0%**	**0.29 [0.08, 1.05]**	
Total events	2		12				

Heterogeneity: Tau² = 0.00; Chi² = 0.46, df = 2 (P = 0.79); I² = 0%
Test for overall effect: Z = 1.89 (P = 0.06)

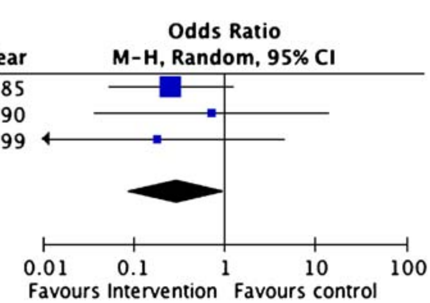

Fig. 5. Incidence of metatarsal stress fractures—from the pooled data, there is a trend that suggests that insoles prevent metatarsal stress fractures, but it is not conclusive

As with all clinical trials, it is important to consider the clinical relevance of these findings and whether or not they justify a change in clinical practice. Because standard insoles are easily used, inexpensive, and pose little risk, any reduction in stress fractures might justify their use. In subgroup analyses, the use of insoles was associated with a lower risk of femoral (OR=0.44, 95% CI 0.25–0.78) and tibial (OR=0.52, 95% CI 0.33–0.83) stress fractures. However, when the 95% confidence intervals are considered, the overall effect of insoles preventing stress fractures (OR=0.54, 95% CI 0.29–1.01) is less conclusive.

The Cochrane Database of Systematic Reviews has published reviews that address the use of insoles for preventing and treating stress fractures [31, 32]. Gillespie et al. evaluated four of the five studies included in this review and an additional study performed by Smith et al. [9, 16, 26–28]. The study by Smith et al. was excluded from this study because "tibial stress" was a primary outcome measure. Gillespie et al. pooled the data from Andrish et al., Milgrom et al., and Schwellnus et al. using a fixed effects model to perform a meta-analysis. They concluded that insoles significantly reduce the number of overall stress fractures in military recruits [31].

Rome et al. assessed six studies: four of which are included in this review, an additional unpublished manuscript, and a study by Mundermann et al. that was excluded from this analysis because "stress fracture or pain" was the primary outcome [14, 15, 27, 28, 31]. In this review, data were not pooled, but relative risks with 95% confidence intervals were calculated for each study. The authors indicate that they used a random effects model, but tabulated data are presented as "relative risk (fixed)", suggesting a fixed, not random, effects model. Noting these concerns, they concluded that the evidence from randomized trials, although limited, suggests that the use of shock-absorbent insoles may reduce the overall incidence of stress fractures in military recruits. Both reviews agree that the available evidence is poor in quality, but neither review commented on how study bias or the variation in exposure may have affected the results [31, 32].

In this way, it is important to note that none of the investigation included in this review performed an a priori sample size calculation. Thus, those studies finding no significant difference between insole and control groups cannot discount the possibility of type II error. This methodological fault is more concerning when the pooled data are reviewed closely. In Figs. 3 and 4, the aggregated data indicate that insoles may indeed lower the incidence of femoral and tibial stress fractures where the overall incidence was not significantly different between groups. However, without an appropriately powered sample size calculation, such a post hoc subgroup analysis should be interpreted with caution. In order to stratify the stress fracture incidence by anatomic site, additional well-designed research would be necessary using a larger sample size with adequate enrolment.

Other methodological concerns warrant consideration. In the study by Milgrom et al., 30 subjects assigned to the insole group discontinued using the insoles due to discomfort in the first 14 days of the trial. Rather than complete an intent-to-treat-analysis, the authors elected to exclude these participants from the final analyses [28]. Similarly, Andrish et al. did not provide an intent-to-treat analysis for participants that crossed over between groups. Instead, outcomes from platoons that did not adhere to their group assignment were combined with the control group for analysis [9].

Finestone et al. assigned 18 soldiers to the insole groups at the onset of the study. When they did not wear the insoles as directed, their data were treated as a second "control group" and pooled with the original controls in the statistical analysis [14]. A secondary analysis reported by Finestone et al. based on intent-to-treat manner found no significant difference between groups (p=0.14). This lack of significance persisted after excluding withdrawals (p=0.07).

Recognizing that the size of the study by Andrish et al. might influence the conclusions from the pooled data, a separate analysis was completed without these data. When the same random effects model was applied to the abbreviated data set, no substantial change was present in the resulting odds ratios. The overall and metatarsal estimates continued to trend toward a reduction in the incidence of stress fractures, while the significant reduction of femoral and tibial stress fractures persisted.

Based upon the best available evidence, shoe insole modification may reduce overall stress fracture incidence during military training, but the findings of these studies are heterogeneous and inconclusive at the present time. From this systematic review, there is compelling evidence that insoles may reduce femoral and tibial stress fractures; however, additional studies are necessary in order to stratify the analysis by anatomic site. Given the current evidence, it is unclear whether the use of insoles would prevent stress fractures in a high risk athletic population. Well-designed studies are necessary to determine the efficacy of insoles as a preventive intervention in an athletic population.

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Appendix. Rationale for exclusion of individual manuscripts

1. Simkin et al. 1989—this study was excluded as it uses the same data as the study of Milgrom et al. in 1985 [24, 28].
2. Milgrom et al. 1992—this study was excluded because it does not meet inclusion criteria. The intervention in this study was not an insole, but a basketball shoe [10].
3. Ekenman et al. 2002—this study was excluded because it does not meet inclusion criteria. Stress fracture incidence is not included as an outcome measure. Instead, the primary outcome measure was reported as "in vivo strain measurement", as determined by in vivo bone staples and strain gauges [19].
4. Larsen et al. 2002—this study was excluded because it does not meet inclusion criteria. Stress fracture incidence is not included as an outcome measure. Outcome measures included self-reported "back problems", "knee

problems”, “shin splints”, “achilles tendonitis”, “sprained ankle”, and “other lower extremity problems” [22].

5. Finestone et al. 2004—this study was excluded because it does not meet inclusion criteria. Within the study design, there was no control group. The study compared outcomes among subjects wearing custom soft orthoses, soft prefabricated orthoses, semirigid biomechanical orthoses, and semirigid prefabricated orthoses [33]. However, there was no control group in which no insoles or standard orthoses were used.
6. Smith et al. 1985—this study was excluded because it does not meet inclusion criteria. The authors used the terminology “tibial stress” as a primary outcome measure, which may indicate stress fractures or tibial stress reactions [16]. Because stress fracture incidence was not specifically reported as an outcome measure, it was excluded.
7. Mundermann et al. 2001—this study was excluded because it does not meet inclusion criteria. The study does not clearly report stress fractures as an outcome measure. The primary outcome measure was described using the terminology “stress fracture or pain” [15]. Because the authors grouped pain with stress fractures, no clear stress fracture incidence could be determined.
8. Withnall et al. 2006—this study was excluded because it does not meet inclusion criteria. The primary outcome reported in this study was “any lower limb injury” [25]. Stress fracture incidence was not reported as an outcome measure.
9. Hinz et al. 2007—this study was excluded because it did not meet inclusion criteria. The primary outcome measure was “peak pressure under metatarsal heads” [21]. Stress fracture incidence was not reported as an outcome measure.

References

1. Arendt E et al (2003) Stress injuries to bone in college athletes: a retrospective review of experience at a single institution. Am J Sports Med 31(6):959–968
2. Goldberg B, Pecora C (1994) Stress fractures: a risk of increased training in freshmen. Physician Sportsmed 22(3):68–78
3. Hame SL et al (2004) Fractures in the collegiate athlete. Am J Sports Med 32(2):446–451
4. Johnson AW, Weiss CB Jr, Wheeler DL (1994) Stress fractures of the femoral shaft in athletes—more common than expected. A new clinical test. Am J Sports Med 22(2):248–256
5. Brudvig TJ, Gudger TD, Obermeyer L (1983) Stress fractures in 295 trainees: a one-year study of incidence as related to age, sex, and race. Mil Med 148(8):666–667
6. Pester S, Smith PC (1992) Stress fractures in the lower extremities of soldiers in basic training. Orthop Rev 21(3):297–303
7. Protzman RR, Griffis CG (1977) Stress fractures in men and women undergoing military training. J Bone Joint Surg Am 59(6):825
8. Matheson GO et al (1987) Stress fractures in athletes. A study of 320 cases. Am J Sports Med 15(1):46–58
9. Andrish JT, Bergfeld JA, Walheim J (1974) A prospective study on the management of shin splints. J Bone Joint Surg Am. 56 (8):1697–1700
10. Milgrom C et al (1992) Prevention of overuse injuries of the foot by improved shoe shock attenuation. A randomized prospective study. Clin Orthop Relat Res (281):189–192
11. Popovich RM (2000) Effect of rest from running on overuse injuries in army basic training. Am J Prev Med 18(3 Suppl):147–155
12. Schwellnus MP, Jordaan G (1992) Does calcium supplementation prevent bone stress injuries? A clinical trial. Int J Sport Nutr 2 (2):165–174
13. Scully TJ, Besterman G (1982) Stress fracture—a preventable training injury. Mil Med 147(4):285–287
14. Finestone A et al (1999) Prevention of stress fractures using custom biomechanical shoe orthoses. Clin Orthop Relat Res (360):182–190
15. Mundermann A, Stefanyshyn DJ, Nigg BM (2001) Relationship between footwear comfort of shoe inserts and anthropometric and sensory factors. Med Sci Sports Exerc 33(11):1939–1945
16. Smith W, Walter J Jr, Bailey M (1985) Effects of insoles in coast guard basic training footwear. J Am Podiatr Med Assoc 75 (12):644–647
17. Wright JG, Swiontkowski MF, Heckman JD (2003) Introducing levels of evidence to the journal. J Bone Joint Surg Am 85-A (1):1–3
18. Spindler KP et al (2005) Reading and reviewing the orthopaedic literature: a systematic, evidence-based medicine approach. J Am Acad Orthop Surg 13(4):220–229
19. Ekenman I et al (2002) The role of biomechanical shoe orthoses in tibial stress fracture prevention. Am J Sports Med. 30(6):866–870
20. Finestone A et al (1992) A prospective study of the effect of the appropriateness of foot-shoe fit and training shoe type on the incidence of overuse injuries among infantry recruits. Mil Med 157(9):489–490
21. Hinz P et al (2008) Analysis of pressure distribution below the metatarsals with different insoles in combat boots of the German Army for prevention of march fractures. Gait Posture 27(3):535–538
22. Larsen K, Weidich F, Leboeuf-Yde C (2002) Can custom-made biomechanic shoe orthoses prevent problems in the back and lower extremities? A randomized, controlled intervention trial of 146 military conscripts. J Manipulative Physiol Ther 25(5):326–331
23. Moher D et al (1999) Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of reporting of meta-analyses. Lancet 354 (9193):1896–1900
24. Simkin A et al (1989) Combined effect of foot arch structure and an orthotic device on stress fractures. Foot Ankle 10 (1):25–29
25. Withnall R, Eastaugh J, Freemantle N (2006) Do shock absorbing insoles in recruits undertaking high levels of physical activity reduce lower limb injury? A randomized controlled trial. J R Soc Med 99(1):32–37
26. Gardner LI Jr et al (1988) Prevention of lower extremity stress fractures: a controlled trial of a shock absorbent insole. Am J Public Health 78(12):1563–1567
27. Schwellnus MP, Jordaan G, Noakes TD (1990) Prevention of common overuse injuries by the use of shock absorbing insoles. A prospective study. Am J Sports Med 18(6):636–641
28. Milgrom C et al (1985) A prospective study of the effect of a shock-absorbing orthotic device on the incidence of stress fractures in military recruits. Foot Ankle 6(2):101–104
29. Mayer D (2004) Essential evidence-based medicine. Cambridge University Press, Cambridge
30. Gordis L (2000) Epidemiology, 2nd edn. Saunders, Philadelphia
31. Gillespie W, Grant I (2005) Interventions for preventing and treating stress fractures and stress reactions of bone of the lower limbs in young adults. Cochrane Database Syst Rev (2): CD000450
32. Rome K, Handoll H, Ashford R (2005) Interventions for preventing and treating stress fractures and stress reactions of bone of the lower limbs in young adults. Cochrane Database Syst Rev (2):CD000450
33. Finestone A et al (2004) A prospective study of the effect of foot orthoses composition and fabrication on comfort and the incidence of overuse injuries. Foot Ankle Int 25(7):462–466