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Foot Orthoses in the Prevention of Injury in Initial Military Training

A Randomized Controlled Trial

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Investigation performed at Britannia Royal Naval College, Dartmouth, Devon, United Kingdom

Background: Overuse lower limb injury is common in incidence and morbidity. Many risk factors, gait related and biomechanical, have been identified, although little conclusive evidence has been found in terms of injury prevention to date.

Hypothesis: Orthoses, as produced by proprietary software interpretation of plantar pressures, are able to reduce injury rates in an ''at risk'' military population.

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

Methods: Four hundred military officer trainees were assessed by means of pressure plate recording of their contact foot pressures during walking. Participants were risk assessed and randomized to receive or not receive customized orthoses using the D3D system. Both cohorts were followed up for injury through their basic training at the 7-week point.

Results: The orthotic intervention group sustained 21 injuries in total (1 injury per 4666 hours of training), whereas the control group sustained 61 injuries in total (1 injury per 1600 hours of training) ($P < .0001$), thereby demonstrating an absolute risk reduction of 0.49 from use of the orthoses ($P < .0001$, chi square; confidence interval, 1.7, 2.4).

Conclusion: In this military trainee population, orthoses were effective in the prevention of overuse lower limb injury. This is the first study to identify a positive preventive role of orthoses.

Keywords: orthoses; injury prevention; athletic injuries; military training; randomized controlled trial

Overuse lower limb injuries are common in initial military training[6,30,32,43] and include medial tibial stress syndrome, stress fractures, anterior knee and patellofemoral pain, Achilles tendinopathy, and plantar fasciitis. Much of initial military training involves a rapid increase in the volume and intensity of running.[19,20,35] Although the incidences of injury are high in the military, at 20% to 50%,[15] they are comparable with those in the nonmilitary running population, at 25% to 65%.[37]

The origins of overuse lower limb injuries are multifactorial,[13,24] with abnormal gait biomechanics being recognized as a critical factor.[3] There has been much work in the prediction of lower limb injury with regard to individual risk factors,[2,15,40] but these are difficult to generalize across all injuries because of a lack of distinct high-quality robust trials toward the effectiveness of interventions in overuse injury prevention. Cross-sectional studies, though allowing for the relationship between potential risk factors and injury to be explored, do not allow a causal relationship to be demonstrated—hence, the need for prospective studies.

The associated morbidity with overuse lower limb injury is significant, and time away from training is important both in the military and for the recreational athlete, in terms of not only financial cost but also an individual's physical and mental health. It has been suggested that preventive strategies be adopted on a clinical and health economic basis.[27]

One commonly cited extrinsic factor affecting overuse injuries in the lower limbs is that of rapid onset of training volume and load.[11] Appropriate intervention in the reduction of overuse injuries is the graduated buildup of training

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load, and this is certainly effective in recreational runners[29] but less easily structured in the military, owing to time constraints.

A number of recent studies have focused on intrinsic risk factors.[12,41] Plantar pressure data have been shown to be comparable to kinematic data in terms of gait-related risk factors,[40] and a number of pressure plate manufacturers (RSscan International, TekScan Ltd) supply proprietary software that, via an interpretation of the data, suggests an orthoses intervention prescription.

Foot orthoses have been commonly used in the treatment of overuse lower limb injuries. However, their proposed mechanism of effect on gait modification is controversial, and the often-quoted mechanical block to abnormal motion as a mechanism of action remains speculative.[22,26] In a high-quality meta-analysis, Collins et al[5] demonstrated a positive effect of orthoses use on prevention of overuse injuries in the lower limbs. The mechanism of action of this beneficial effect is still not understood but is likely to involve muscle activation,[40] thereby controlling rate or excessive pronation during the stance phase of the gait cycle.[36]

Further evidence to guide the prophylactic prescription of foot orthoses with the aim of injury reduction is important given the widespread use of such devices in this environment and the lack of evidence behind their use.[22,26]

We assessed the effect of semicustom orthoses produced by the D3D system (RSscan Lab Ltd, Ipswich, United Kingdom) in initial military training in a randomized controlled trial. The D3D orthotic is an ethylene vinyl acetate orthosis, with a degree of computer-aided customization based on pressure plate gait assessment. We hypothesized that there would be a reduction in injury rates with the intervention of the D3D orthotic as compared to those without orthoses.

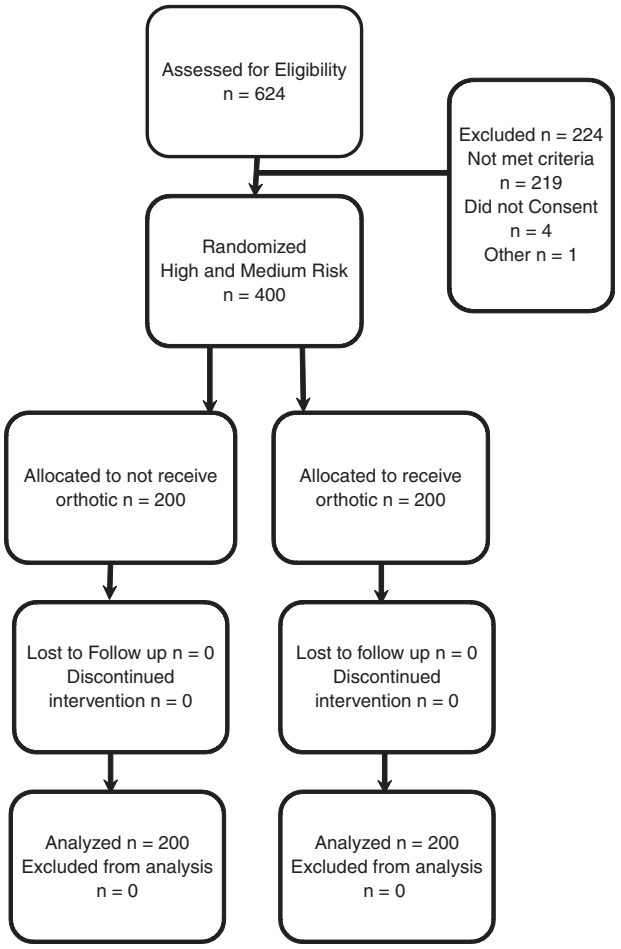

Figure 1. CONSORT diagram of the flow of participants through study.

MATERIALS AND METHODS

We conducted a randomized controlled trial in an initial military training establishment in accordance with the CONSORT statement (Figure 1). All new-entry officer cadets to the Britannia Royal Naval College were asked to volunteer. Eligibility criteria were all new-entry officer cadets. Exclusion criteria were preexisting orthotic use, previous lower limb injury (<6 months), and consent withdrawal.

The Britannia Royal Naval College is set 175 ft (52.50 m) above sea level; as such, much running is uphill and downhill. New-entry trainees follow a progressive gym- and running-based program revolving around personal fitness. They are given a standardized prejoining training program. Compliance with this program was not assessed, but all participants met the minimum standard for joining. Minimum personal fitness standards require the completion of 1.5 miles (2.4 km) in less than 11 minutes, 13 seconds, for 25-year-olds and less than 11 minutes, 38 seconds, for 26- to 30-year-olds.

As part of the curriculum, 2 or 3 periods of daily physical training are carried out (at a minimum), including gym-based activities, squad running, and outdoor marching and load carrying. Daily load and mileage gradually increases to a maximum of 27 miles (43.20 km) in 48 hours, carrying a personal load of 30 kg at the end of 7 weeks. The remainder of the program is classroom- or riverboat-based activity.

Injury Surveillance

All participants underwent the same training program. Participants were recruited from serial new-entry intakes; thus, there were minor seasonal changes in weather and ground hardness, but the program remained constant.

The trial commenced in December 2005 and was completed in July 2007, and the participants' medical records were searched for injury reported at the 7-week point. Where no diagnosis of injury had been made, a manual search of the electronic record over a 7-week period was conducted. As part of an initial military training establishment, participants must report any injury or illness to the medical facility if they are to miss any academic or training serial; as such, injury reporting is comprehensive.

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Protocol

Participants gave written informed consent, and the study had human ethics approval from the Ministry of Defence Research Ethics Committee. Participants' anthropometric data were recorded; then, the initial pressure plate measurements were taken in the week of commencement of all officers. No physical exercise sessions were carried out in the 24 hours before testing. The outcome measure (injury; see definition below) was followed up across phase 1 of training (7 weeks).

All participants were asked to walk barefoot at natural gait over the gait assessment test track on a number of acclimatization walks, until they felt comfortable. Plantar pressure data were recorded with a pressure plate (RS scan International, Olen, Belgium): 1.00 × 0.40 × 0.02 m, 64 lines at 500 Hz and 3 sensors per cm^2 (8192 total sensors), placed flush in the center of an 18-m track of 0.02 m ethylene vinyl acetate covered in a 0.005-m rubber track cover. Participants were asked to walk across the apparatus at a natural gait a minimum of 5 times on both the right foot and the left.

The run was considered valid when a heel strike pattern was captured, with only the right or left foot strike pattern recorded per run. The recordings were averaged, which gave a classification of risk as created by the authors (described below).

Risk Quantification

Eight anatomical areas are automatically identified by the plantar pressure software (Footscan 7.0 Gait 2nd Generation, RSscan International) based on peak pressure footprint (Figure 2). These areas are defined as medial heel (H_M), lateral heel (H_L), metatarsal heads (M_1, M_2, M_3, M_4, M_5), and the hallux (T_1). Temporal data on time to peak pressure, peak pressure, and impact are recorded for each area. These data are interpreted by the software to determine a ratio among rearfoot, midfoot, and forefoot areas (Table 1); should these ratios deviate from a range as determined by the manufacturer, a correction is recommended in this area of foot contact, to be applied to a custom orthosis with up to 4 areas of correction.

For the purposes of this study, participants were risk quantified to the number of corrections, 0 to 4, as recommended by the software, with *low risk* being no corrections, *medium risk* being 1 correction, and *high risk* being 2 or more corrections.

Interventions

Participants at risk (ie, those with a medium or high risk) were included in the trial and randomly allocated by random integer generator (http://www.random.org) to either the intervention group or no-intervention group, not blinded to the investigators.

Participants were blind to their risk quantification and to whether they were allocated orthoses because of low risk or because they were in the nonintervention arm. The intervention itself was not blinded. The intervention involved customized D3D orthoses. The D3D orthoses were a modular injection-molded device, available in different densities and arch profiles to accommodate for dynamic foot type and body weight and further customized depending on the participant's need. The orthotic prescription (identified by code) was e-mailed to the company after testing, and an orthosis was generated and sent by mail. Participants commenced wearing of the orthoses 4 ± 1 days after testing, based on an acclimatization protocol that increased the wearing of the orthoses by 1 to 2 hours a day across a 5-day period. The nonintervention participants received neither a shoe insert nor an orthosis.

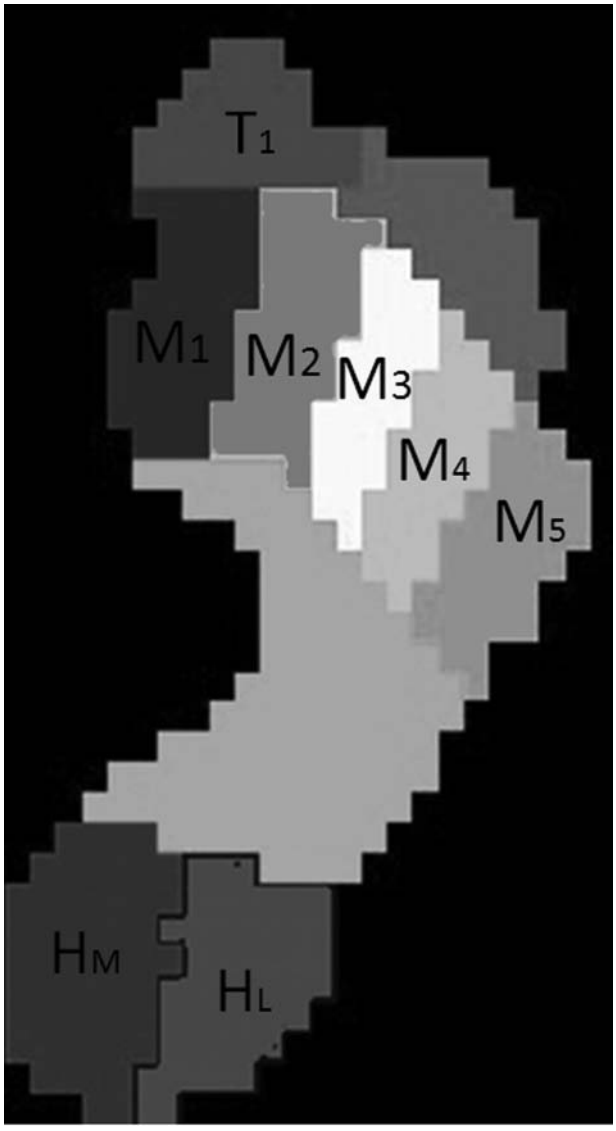

Figure 2. The 8 anatomical areas as divided by pressure plate software.

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TABLE 1
Areas of Orthotic Correction and Calculation Pressure Areas

Correction[a]	Calculation[b]
A+, forefoot correction (antipronation)	$(M_1 + M_2) / (M_1 + M_2 + M_3 + M_4 + M_5)$
DF-, anti-inversion element, lateral stabilizer	$(M_3 + M_4 + M_5) / (M_1 + M_2 + M_3 + M_4 + M_5)$
B+, midfoot correction (antipronation)	$(M_1 + M_2 + H_M) / (M_1 + M_2 + M_3 + M_4 + M_5 + H_M + H_L)$
C, rearfoot correction (antivalgus)	$(H_M) / (H_M + H_L)$

[a]A+, DF-, C, and B refer to areas addressed for potential correction as applied to the orthoses.
[b]H_M, medial heel; H_L, lateral heel; M_1, M_2, M_3, M_4, M_5, metatarsal heads.

Outcomes

The primary outcome measure was that of overuse lower limb injury requiring removal from physical training for 2 or more days. Overuse injury required a diagnosis of anterior knee pain, iliotibial band syndrome, patellofemoral pain syndrome, medial tibial stress syndrome, chronic exertional compartment syndrome, Achilles tendinopathy, or plantar fasciitis. The initial diagnosis was made by fresh presentation to nursing staff, and diagnosis was confirmed by a single sports physician. This was recorded on the primary care medical record system (EMIS, Leeds, United Kingdom), as was time away from training. Repeat injuries were recorded as a single injury.

Sample Size

The primary endpoint for the trial is the group proportion of participants injured. The research question is whether those who wear orthoses are less likely to be injured when compared with those who do not wear orthoses in the test period. A pilot study suggested that overall injury risk was 29.6% for both groups. The sample size was designed with an effect size of 10% reduction (with 80% power and $\alpha = .05$) based on the following assumptions:

Null hypothesis: The injury rate is the same among participants who wear orthoses and those who do not.
Alternative hypothesis (one sided): The injury rate is less among those who wear orthoses compared with those who do not.

We based the sample size calculations on a previous unpublished pilot study that showed that a sample size of 190 in each group was sufficient to detect a difference between groups: $P < .05$ with 95% confidence interval and 80% power, $\alpha = 0.5$ (PASS 2005 software, NCSS, Kaysville, Utah), and McNemar test applied to correlated data. Two hundred participants were recruited in each group to allow for potential dropout.

Statistical Analysis

Statistical analysis was performed with SPSS 15 (SPSS Inc, Chicago, IL). Comparison between intervention injury rate and nonintervention injury rate was compared with chi-square test.

TABLE 2
Anthropometric Data for Patients[a]

	Orthoses (n, 200)	Control (n, 200)
Age	24.75 (24.68, 24.82)	24.9 (24.83, 24.97)
Male:female patients, %	68:32	62:38
Height, cm	180 (179.93, 180.07)	178.9 (178.83, 178.97)
Mass, kg	77.2 (77.13, 77.27)	79.2 (79.13, 79.27)
Shoe size (UK)	9.5 (9.43, 9.57)	10.0 (9.93, 10.07)

[a]Confidence interval (95%) in parentheses.

The endpoint was the end of the initial military training phase at 7 weeks. The data were analyzed with respect to relative risk reduction and number needed to treat.

RESULTS

From December 2005 to June 2007, 624 participants were assessed and 400 enrolled in the study. Figure 1 details the participant flow in accordance with the CONSORT statement. In sum, 219 participants were excluded from the trial, demonstrating low risk at biomechanical assessment; 4 declined to give informed consent; and 1 participant was admitted to the hospital with a medical condition and left the service. Anthropometric data were well matched between the 2 groups (Table 2).

There are situations where a participant may elect not to present and train with an injury, but this is no different from the population at large and would thus result in an underreporting rather than an overreporting of effect size.

The chi-square test was used to investigate if there was an association between injury risk reduction and orthoses use. The results showed that there was a strong association between orthotic prescription and injury reduction ($\chi^2 = 34.39$, $df = 1$, $P < .0001$). All 200 participants were analyzed in each arm using an intention-to-treat analysis.

Overall, 82 injuries were sustained by participants in the duration of this study. The most frequently recorded injury was medial tibial stress syndrome (Table 3), which is consistent with previous overuse injury studies, followed by iliotibial band syndrome and Achilles tendinopathy.[21,38] The range of injuries is consistent with that of other reported studies.[4] There was an increase in plantar

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TABLE 3
Breakdown of Injuries Sustained by Group and Type

Diagnosis	Control Group		Orthoses Group		Mean Days Withdrawn From Training
	Male (n, 136)	Female (n, 64)	Male (n, 124)	Female (n, 76)	
Tibial stress fracture[a]	1	1	0	1	74
Metatarsal stress fracture[a]	2	1	1	0	55
Femoral neck stress fracture[a]	0	1	0	0	122
Patellar tendinopathy[b]	1	1	3	1	8
Iliotibial band syndrome[b]	11	0	3	1	6
Medial tibial stress syndrome[b]	18	4	2	0	13
Chronic exertional compartment syndrome[b]	7	0	1	0	4
Achilles tendinopathy[b]	7	1	2	2	5
Plantar fasciitis	5	0	4	0	9
Total	52	9	16	5	—

[a]Stress fracture confirmed by plain film and magnetic resonance imaging.
[b]Diagnosis confirmed by physical examination and clinical signs.

TABLE 4
Results Comparing Injury Rate and Injuries Between Groups[a]

Group	Risk	Patients, n	Injuries, n	Injury Rate:Hours Training
Control	High/medium	200	61	1:1600
Orthotic	High/medium	200	21	1:4666
Absolute risk reduction		CER − EER (0.74 − 0.25) = 0.49		
Number needed to treat		1 / 0.49 = 2		

[a]Chi-square, $P < .0001$. CER, control event rate (74%); EER, experimental event rate (25%).

fasciitis in the intervention arm. The overall injury rate of the participants in the study was 20%.

Men and women complete identical training, and their data were reported together. When the absolute risk reduction was analyzed independently, it was 0.44 for men but 0.04 for women.

The orthotic intervention group sustained 21 injuries in total (1 injury per 4666 hours of training), whereas the control group sustained 61 injuries in total (1 injury per 1600 hours of training) ($P < .0001$), thus demonstrating an absolute risk reduction of 0.49 from use of the orthoses ($P < .0001$, chi square; confidence interval: 1.7, 2.4) (Table 4).

There were reported side effects of the intervention orthoses, but these were confined to foot blisters, and a similar number presented in the control group (intervention: n, 12; control: n, 16). New-entry trainees spend most of the day and night in standard-issue high-leg boots and thus commonly report foot blistering in the initial phases of training. There were no withdrawals from either arm of the trial, and no orthoses were returned because of damage or noncompliance. Table 3 reports the mean number of withdrawal days from training for each injury type.

DISCUSSION

This study demonstrated a significantly reduced rate of exercise-related lower limb injury across the training period for those at risk who wore D3D orthoses. In a well-constructed randomized controlled trial, we looked to identify a reduction in lower limb injury by the use of custom orthoses when a need was identified based on biomechanical assessment of gait. Participants were not treated with orthoses; they were prescribed orthoses to prospectively reduce the risk of injury.

There was a lower-than-expected injury rate in the overall trial at 20% against an expected rate nearer 30%, which can be explained by the reduction of injury rates in the intervention arm.

Previous retrospective studies have identified increased pronation excursion, including eversion, abduction, and dorsiflexion results in increased risk of overuse injury in the lower limbs.[12,40] Prospective studies assessing plantar pressure recordings have highlighted the rate of pronation and the reinversion rate in overuse injuries, resulting in higher medial-pressure readings and more central-heel contact,[40] as well as more laterally loaded initial contact and toe-off.[12] All of these would result in a correction

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recommendation by the D3D software and increase the risk stratification of the participant.

The benefit of orthoses is not new in terms of injury treatment. Studies comparing orthoses with local anesthesia and corticosteroid injection in the treatment of plantar fasciitis show some benefit,[18] particularly in studies where patient satisfaction is considered.[16]

There was a significant difference between the absolute risk reduction in men and that in women. However, although women were injured less frequently, their injury profile (ie, predominantly stress fractures) was different from the men's, and the number of injuries is too small to draw any statistical conclusions.

There were differences between the 2 groups of participants with respect to anthropometry. The controls were statistically heavier, shorter, and had larger feet. The literature suggests that increased body mass is an independent risk factor for lower limb overuse injuries.[31,37] If this is a true confounding variable, then one can expect a higher incidence of injury.

In terms of injury prevention, there has been much discussion over the use of shock-absorbing insoles. Withnall et al[42] performed a large randomized controlled trial comparing various types of insoles to injury over initial military training and found no difference in injury rate among any of the cohorts. This finding is supported by a study comparing orthotic prescription with simple insoles in the prevention of stress fractures,[9] suggesting that noncustom insoles have little role in injury prevention. The literature does not support the custom casting for orthoses in injury treatment or prevention, finding little difference in prefabricated and custom-modeled orthoses.[10,28] This supports our study, which used noncast orthoses modified to correct biomechanical abormalities but not molded.

The mode of action of the orthoses-related injury reduction is still not clear. Willems et al,[40] using the same recording and analysis system, concluded that central heel strike, excessive eversion, and increased lateral rolloff were independent risk factors for exercise-related lower limb injury. Dixon and McNally[7] demonstrated that adding an orthosis to a neutral shoe resulted in significant changes to the pressures below the shoe, confirming that a D3D orthosis could alter gait, although they did not elucidate by which mechanism.

Murley et al,[23] in their comprehensive systematic review, highlighted some evidence of increased electromyogram amplitude of the tibialis anterior and peroneus longus with foot orthoses[23,25] and evidence of electromyogram muscle activity changes in hindfoot wedging and heel cup support.[14] They did conclude that study methodology is inconsistent and that it is difficult to tell whether muscle activation changes in the normal individual are consistent when wearing an orthoses. It is likely that the orthotic device changed the muscle activation of the control musculature of the foot during the gait cycles, but further work needs to address this important question. From this study, it is impossible to say what the beneficial effect is attributable to.

In this study, the greatest reduction of injury type was seen in medial tibial stress syndrome, iliotibial band syndrome, and Achilles tendinopathy. All have been linked to the lack of control of gait-related factors,[12] and we postulate whether this control is enhanced in some way by the orthotic intervention, although this study is not powered to identify attributable risk reduction between individual injury diagnosis and orthotic intervention. The simplicity of the outcome measure reduced the influence of bias and was able to directly answer the hypothesis in terms of an all-causes overall injury rate reduction.

Strengths and Limitations

A weakness of the study design was the elective decision not to use dummy orthoses in the control group. We discussed this at length and thought that even the use of a nonformed ethylene vinyl acetate insert would increase the shock-absorbing characteristics of the boot, improve heel fitting, and thus create a confounding variable. The aim of the study was to compare the effect of orthoses on injury prevention, and the direct comparison was made as such. We accept that there lies a placebo effect; however, the outcome measure was that of lower limb injury.

In this study, data were analyzed simply as binary—all risks injured or not. This tells us little about an individual's pressure plate analysis and his or her subsequent injury type or risk thereof. We were aware of the insufficient power to perform this multivariate analysis and did not perform such an analysis. This would be of significant interest in future studies in terms of prediction of high morbidity and time loss to injuries, as well as in intervention programs for injury reduction.

There were significant strengths in using a standardized training regimen in an initial military training establishment, which allowed comparatively large numbers of participants to be included. Further to this environment, the dropout and lost-to-follow-up rate was nil, thereby increasing its strengths.

There are significant confounding variables in the causes of overuse lower limb injury, ranging from pretraining program, previous exercise levels, smoking status, and menstrual history to training intensity, alcohol consumption, and running shoes.[1,8,34,39] Any study attempting to measure all known possible variables would not succeed. We accept there are confounding causal factors and do not propose that orthoses are the panacea, but our study suggests that they are part of the armor in the prevention of lower limb injuries.

Economics

The orthoses used in this trial were not custom-molded rigid orthoses but ethelene vinyl acetate–molded orthoses with 4 specific fixed areas of variable correction applied, where the D3D software recommended. The orthoses were manufactured at a cost of £45/$73 per pair. This, of course, excludes consultation time and the capital costs of the testing apparatus; thus, a full cost-benefit analysis should be performed. But the potential cost savings in terms of injury prevention and reproducibility of orthotic device appear significant.

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Collins et al,[5] in their systematic review, identified 2 studies[17,33] addressing the cost-effectiveness of orthotic interventions, but these were in specific clinical scenarios, and their relevance to this study is limited.

CONCLUSION

The causes behind lower limb injuries are much the same in recreational running[24] as in initial military training such that these findings can be extrapolated outside the military setting. Within the military environment, initial military training at Britannia Royal Naval College is not infantry training; as such, care should be taken before extrapolating this setting to the basic infantry training setting. However, the underlying mechanisms of injury are the same in any setting. The quantifiable difference is the intensity and volume of the training load, and we would expect a comparable injury reduction in other populations.

The foot orthoses in this study, D3D, conferred a statistically significant degree of overuse lower limb injury prevention. The preventive results can be cautiously extrapolated to a recreational running setting and should be considered by sports and exercise medicine professionals.

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