# Prevention of Lower Extremity Stress Fractures: A Controlled Trial of a Shock Absorbent Insole

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Abstract: A prospective controlled trial was carried out to determine the usefulness of a viscoelastic polymer insole in prevention of stress fractures and stress reactions of the lower extremities. The subjects were 3,025 US Marine recruits who were followed for 12 weeks of training at Parris Island, South Carolina. Polymer and standard mesh insoles were systematically distributed in boots that were issued to members of odd and even numbered platoons. The most important finding was that an elastic polymer insole with good shock absorbency properties did not prevent stress reactions of bone during a 12-week period of vigorous physical training. To control for the confounding effects of running in running shoes, which occurred for about one and one-half hours per week for the first five weeks, we also examined the association of age of shoes and cost of shoes with

## Introduction

Stress fractures and stress reactions of the lower extremities have long been considered a hazard of military life and are frequently associated with road marching or high intensity physical training. The occurrence of these injuries has been noted for many decades, <sup>1-5</sup> but only since the mid-1970s have studies with rate calculations been published, yielding a better idea of the serious nature of this problem. Eight studies since 1974 have documented that the stress fracture rate in military recruits varies from 1 to 4 per cent in males and from 10 to 15 per cent in females.<sup>6–13</sup> Injuries of this type, particularly if they occur in the femur, have a protracted hospital course, can be permanently disabling, and lead to a higher rate of medical discharge in affected trainees.

The ideal military training program would allow trainees to pass through a period of bone resorption activity, followed by bone replacement activity, without suffering a stress fracture or periosteal stress reaction.<sup>13</sup> Prevention in military training has therefore focused on reducing the intensity of training in the first few weeks, the period of maximal bone resorption, particularly for trainees who are not physically fit at entrance. Current US Army training policy requires unfit trainees to be exercised more gradually during the first three weeks.\*

One characteristic of the training environment that can be modified easily is the amount of cushioning provided by footwear during training. Lack of cushioning in shoes has been hypothesized for some time as a cause of running

\*US Army Training and Doctrine Command: Physical Training Program of Instruction (letter). October 1985, Fort Monroe, VA. injury incidence. A slight trend of increasing stress injuries by increasing age of shoes was observed. However, this trend did not account for the similarity of rates in the two insole groups. In addition, we observed a strong trend of decreasing stress injury rate by history of increasing physical activity, as well as a higher stress injury rate in White compared to Black recruits. The results of the trial were not altered after controlling for these factors. This prospective study confirms previous clinical reports of the association of stress fractures with physical activity history. The clinical application of a shock absorbing insole as a preventive for lower extremity stress reactions is not supported in these uniformly trained recruits. The findings are relevant to civilian populations. (Am J Public Health 1988; 78:1563–1567.)

injuries.<sup>14–17</sup> Consequently, running shoes are permitted to be worn during training runs in the military in place of the military combat boot.<sup>18</sup> The military combat boot was not designed to be shock absorbent, but to protect the foot and ankle from inversion injuries. An evaluation of Army combat boots found them to be inferior to running shoes in impact protection, flexibility, and energy retrieval.<sup>19</sup> In spite of these shortcomings, many hours of running, marching, calisthenics, and drill take place in combat boots. The simplest means for enhancing impact protection of the boot is to place within it a shock-absorbing insole. If it were to prove efficacious in preventing lower extremity injuries, such an insole could easily be added to the military footwear currently issued to each recruit.

The Sorbothane insole (IEM Orthopaedics, Aurora, Ohio), a viscoelastic polymer, was manufactured to absorb up to 95 per cent of the impact stress transmitted from the ground to the lower extremities. The following report describes a 1985 trial of the effect of Sorbothane insoles, as compared to a standard insole made of mesh, in prevention of stress fractures and stress reactions of bone.

## Methods

## Subjects

The subjects of this study were 3,025 United States Marine basic training recruits, with a mean age of 20.0 years  $\pm$  .02, range 18 to 41, who underwent 12 weeks of basic training at the Marine Training Center at Parris Island, South Carolina. Sixty-seven per cent of the trainee population was White non-Hispanic, 24.6 per cent was Black non-Hispanic, 5.6 per cent was Hispanic, 0.7 per cent was Native American, and 1.5 per cent was of other ethnic origin.

#### Questionnaire

Recruits completed a questionnaire after hearing each item read aloud by an instructor to ensure comprehension. Questions were included which determined the recruits' usual physical activity status (very active, active, average, not very active, inactive) prior to their arrival at Parris Island, and the age, condition, and cost of their running shoes used during training.

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## **Physical Training Program**

Trainees participated in 92 hours of physical training (road marches, calisthenics, running, rappelling, and swimming) and 41.5 hours of drill and ceremony during a 12-week stay at Parris Island. Of the time devoted to physical training, only the hours devoted to swimming and ceremony (19 hours) did not expose the trainees to the risk of lower extremity injury. Since 1976, the Marine Corps has allowed trainees to run in footwear other than boots, and about nine hours of training were spent running while wearing running shoes (recruit-purchased, not issued). Most of the running in shoes (80 per cent) occurred during the first five weeks of training. While the style and condition of the running shoes were not under control, the answers to questions about the condition of the shoes allowed some control for their effect.

Training was done by platoon unit—a group of approximately 65 persons who shared the same sleeping and eating facilities. During the first week, all trainees were required to take a diagnostic physical fitness test consisting of a one and one-half mile run, pull-ups, and situps. Passing a final physical fitness test consisting of a three-mile run, pull-ups, and situps was a requirement for graduation. Two long marches (seven miles and 10 miles) in boots and full combat equipment occurred in the 4th and 8th weeks, respectively.

## **Trial Design**

Boots with polymer insoles were issued to trainees who were assigned to even-numbered platoons. Boots with a standard mesh insole were issued to members of odd numbered platoons. Exchanging or losing the insoles was minimized in two ways. First, virtually no interaction among trainees from different platoons was permitted, and all trainees within each platoon had the same insole type. Second, trainees were told at the beginning of training and periodically during training that they were to leave the insoles in their boots. Equipment inspections enforced compliance.

## Ascertainment of Injury Endpoints

All Marine recruits who had lower extremity injuries were evaluated at a medical clinic on Parris Island. Injury information for this study was recorded on clinical data forms at the time of the clinic visit. Patients were transferred to Beaufort Naval Hospital for lower extremity x-rays.

Two radiologists independently evaluated the radiographs of injured recruits. The first radiologist, at Beaufort Naval Hospital, gave the primary radiologist's reading of the films. After the study was completed, the x-ray films were re-evaluated by another radiologist at Walter Reed Army Medical Center, Washington, DC. Both radiologists were blinded with respect to insole status and the second review was blinded concerning the primary evaluation.

Endpoint classification was based on functional impairment rather than solely on radiographic demonstration of a clear disruption of the integrity of bone cortex. Thirty-eight trainees had either x-ray-confirmed stress fractures or clinically serious stress reactions with x-ray evidence compatible with stress injury (cortical tunneling or lucency). Since recruits with pain in the lower extremities were managed conservatively, many stress reactions were prevented from progressing by repeated visits to the Parris Island medical clinic, which was open 24 hours a day. A number of individuals had only one film taken and, because of the delay in appearance of radiographic evidence following onset of symptoms, these early x-rays were frequently negative. Rather than drop from the analysis all persons with only early x-ray films, we pooled together x-ray-confirmed stress fractures with stress injuries having an incomplete set of radiographs but clinically significant symptoms and referred to them all as stress fractures.

The distribution of the 38 stress fractures was femur (5), tibia (14), fibula (5), calcaneous (1), and metatarsal (13). Most of these injuries were unilateral, but bilateral injuries occurred in the tibias of four recruits, and in the femurs, calcanei, or metatarsals of one recruit each.

## Statistical Analyses

Fisher's exact test was employed to test the significance of proportions compared in two by two tables.<sup>20</sup> Where questionnaire responses followed an ordered sequence, a chi-square test for trend was employed.<sup>21</sup> All data were collected on mark-sense forms and edited and analyzed using version 4.0 of the Statistical Analysis System.<sup>22</sup>

## Results

Table 1 presents fracture rates by age, ethnicity, and activity status. With only 37 recruits above age 25, the 21+ age group mainly represents the ages 21 to 25. Adjusted for physical activity, the relative risk for older vs younger recruits was 1.71. Whites, compared to other racial and ethnic groups, had a relative risk of 2.45. Intrinsic racial differences in susceptibility to stress fractures are given some support by these data.

Previously inactive trainees were at much greater risk, over 10 times the average of the other four activity categories. The inverse relation of risk to reported physical activity is strong in these data: the chi-square for linear trend was highly significant. Compared to trainees with above average activity levels, the relative risk of fracture for all others was 2.40 (95% C.I.=4.58, 1.26).

As seen in Table 2, the fracture rate for the polymer insole group was slightly higher (1.35 per cent), but not very different from the rate in the standard insole group (1.13 per cent). Activity levels were similar in the two groups. In the less active subgroup and the more active subgroup, the fracture rates did not vary much by insole type.

We examined the fracture rates by location of stress injury (Table 3) to see whether the protective effect of increased shock absorption could be localized to the foot. We found no such effect.

## TABLE 1-Stress Fracture Rates by Age, Ethnicity, and Activity

Variables	Fractures	Trainees	Rates (%)
Age (years)			
18–20 Í	21	2074	1.01
21+	17	934	1.82
Summary* Relativ	/e Risk 18-20 vs 21	+ = 1.71 (95% CI:	0.92. 3.21)
Ethnicity			,,
White NH	32	2050	1.56
Hispanic	1	168	0.60
Black NH	5	743	0.67
Amerindian	Ō	20	_
Other/Unk	Ō	44	
Summary* Relative	Risk white vs all ot	her = 2.45 (95% C	1: 1.06. 5.68)
Activity			
Inactive	3	25	12.00
Below Average	5	224	2.20
Average	15	924	1.62
Active	11	1197	0.91
Very Active	4	638	0.62

\*Adjusted for history of reported physical activity (5 levels).

TABLE 2-	Stress	Fracture	Rates	by	Boot	insole	Туре
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	Total Group	Polymer	Mesh	Relative Risk	95% CI
N/PAR	38 /3025	21/1557	17/1468	1.17	(.62, 2.2)
Per Cent	(1.26%)	(1.35%)	(1.13%)		(
Physical Activity = Average or	<b>(</b> ,	(	(		
Below	23 /1173	13/589	10 /584	1.29	(.57, 2.9)
	(1.96%)	(2.21%)	(1.71%)		( - · · / - · - /
Physical Activity = Active or	、 <i>,</i>		(,		
Very Active	15 /1835	8/960	7/875	1.04	(.38, 2.9)
-	(0.82%)	(0.83%)	(0.80%)		,

Since the cushioning and support from running shoes deteriorates with age, we examined whether the age of shoes was equivalent for polymer and standard insole groups. A modest trend of increasing fracture rates by age of shoes was observed (Table 4). The crude relative risk of 1.17 was unchanged after adjusting for age of shoes with two levels (less than one month, greater than one month). Cost of shoes in relation to fracture rates was examined. The rates varied only slightly among three categories of cost, with no apparent trend (Table 5).

Finally, we examined the differences for polymer vs mesh groups in a category comprising four other major injuries: plantar fasciitis, ankle sprains, knee strains and sprains, and achilles tendonitis (Table 6). Once again, no protective effect from the polymer insole was apparent.

#### Discussion

Published tests of the efficacy of shock absorbent materials in footwear have been few. On the other hand, many citations can be found which recommend the use of shock absorbing shoes or shock absorbent insoles based on a review of clinical cases.<sup>14–17</sup> Our review of the literature uncovered only one prospective study of the efficacy of shock absorbing insoles in preventing any type of overuse injuries. A 1985 study of 90 US Coast Guard recruits reports cushioned insoles successful in reducing "shock impact and shearing injuries"<sup>23</sup>; however, the impact and shearing injuries referred to were foot bruises, calluses, and blisters, not stress fractures or stress reactions. An unpublished 1986 report on the frequency of lower extremity injuries among 555 female Army basic trainees found no difference in stress fracture or stress reaction rates between trainees wearing a Sorbothane

TABLE 3—Iniur	v Rates b	v Insole Ty	vpe Stratified	bv iniurv	Location

		Insole Type		
Location	Injury Type	Polymer	Mesh	
Above the Foot	Stress Fractures	10 /1557 (0.64%)	14 /1468 (0.95%)	
	Other Injuries	233 /1557 (15.0%)	253 /1468 (17.2%)	
Foot	Stress Fractures	11 /1557 (0.71%)	3 /1468 (0.20%)	
	Other Injuries	47 /1557 (3.01%)	38 /1468 (2.59%)	

insole compared to those wearing a standard mesh insole.\*\*

While observations on injuries in military training are not always generalizable to the general population, injury types in this and other military populations resemble civilian population reports. In basic training populations in the Army, five injury types are repeatedly cited as accounting for over 50 per cent of all training injuries: stress fractures, overuse injuries of the knee, plantar fasciitis, achilles tendonitis, and ankle sprains.<sup>6,12,24</sup> These same five injury types are cited as accounting for over 50 per cent of all injuries in civilian running and jogging programs.<sup>14,16,25</sup>

The uniformity of Marine training is advantageous for determining the effect of a simple training modification—the addition to the boot of a shock absorbing viscoelastic insole. Each drill instructor, platoon, and training company follows the same program during the 12-week training cycle. This rigid pattern is in contrast to the exercise patterns of runners presenting at an orthopedic or sports medicine clinic, where the entire spectrum of activity is represented.

The stresses of physical training were greater for those trainees who were initially physically unfit. Previous studies have also noted the association of fitness with injury risk, but they used data collected retrospectively, after the injury had occurred.<sup>26</sup> In contrast, the present study recorded responses to questions before training began. A simple multiple choice response to the question, "How would you describe your life before coming to Parris Island?", proved remarkably sensitive in discriminating trainees at risk of significant stress reactions. For those 25 categorized as "inactive" prior to their training, three (12 per cent) suffered a significant stress reaction. The other responses were associated with progressively lower rates of bone injury.

In civilian populations, the most frequently encountered abrupt change in physical activity is increased or newly adopted running, referred to as "training errors". These errors may be the most important cause of running injuries.<sup>15,16</sup> These clinical observations reflect the importance of what Powell, *et al*, have called "the stability of running habits."<sup>27</sup> Although we cannot give quantitative guidance from these data about the amount of activity change that leads to an injury risk, we can say that previously inactive recruits had a 10-fold excess risk of clinically significant stress reactions during basic training relative to the rest of the recruit population. The impact of the inactive group on the Marines (25 of 3,025) is small, but for the general

<sup>\*\*</sup>Bensel C, Kaplan DB: Wear test of boot inserts. (Report). US Army Natick Research and Development Laboratories, Natick, MA, December 1986.

TABLE 4—Stress Fracture Rates by Age of Shoes

	<1 wk	1 wk-1 mo	1-6 mos	6 mos-1 year	>1 year	Total
N/PAR Bor Cont	20 /1792	7 /630	8 /422	3 /119	0 /44	38 /3007*
affected	1.12	1.11	1.90	2.52	—	1.26

 $\chi^2$  trend = 2.54

One-tailed p = 0.05618 individuals had missing shoe information

population that proportion, and the injury consequences, would be much higher. The traditional recommendation to beginning runners (and the military's requirement for physically unfit trainees) to start slowly and to build up progressively the frequency, intensity, and duration of running, would seem well supported as a policy for preventing significant stress reactions of bone.

The distribution of stress reactions in this study (71 per cent of the total found in tibia or metatarsal) follows closely that observed in similar studies.<sup>11,28</sup> The authors of one study correlated their findings with the use of a heel snap to mark the cadence while marching. The heel snap has since been discontinued.

We observed a slight excess of clinically significant stress reactions of the metatarsals and calcanei in those recruits who used the Sorbothane insole. This excess was reflected, to a lesser extent, in higher overall injury rates below the ankle in the polymer insole group. The picture was reversed above the ankle, with a slight excess of fractures in the mesh insole group, and likewise an excess of all other types of injuries in the mesh insole group. Whether this pattern is causally related to the insole remains an intriguing question that needs testing.

These data also confirm earlier studies' reports of an excess of stress fractures or stress reactions in Whites compared to Blacks.<sup>9</sup> One explanation for this finding could be the lesser bone density and bone mass observed in Whites compared to Blacks.<sup>29–32</sup> If racial differences in bone density are important predictors, studies which can account for both bone density and physical activity history need to be done.

Of the 92 hours of physical training each recruit experienced, nine were spent in running shoes without an insole. Although we did not study running shoes in detail, the age of the shoes and the price paid provided information about

TABLE 5—Stress Fracture Rates by Pri	rice of Running S	Shoes
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	<\$25	\$25-40	\$40+
N/PAR Ber cent	19 /1555	12 /748	7 /722
affected	1.22	1.60	0.97

 $\chi^2$  trend = 0.5

p = n.s.

TABLE 6-Other Serious Lower Extremity Injuries by Insole Type

	Injuries	Trainees	Rate (%)
Polvmer	101	1456	6.40
Mesh	97	1371	6.61

Relative Risk polymer vs. mesh = 0.98 (95% CI: 0.73, 1.31)

condition of the shoes. Price, a correlate of overall quality, perhaps of shock absorbency, did not affect fracture rates, but increasing age of shoes did. The age of the shoe may indicate the degree to which its shock absorbent material has been compacted. On the other hand, the mechanical support provided by a shoe is also adversely affected by age. Without more data, cushioning effects cannot be separated from support effects. We also cannot assess the efficacy of shock absorbing insoles for moderate vs extreme amount of running.

Our findings suggest that the relation between footwear and lower extremity injuries is complex, that the simple model of the lower extremity as a projectile impacting upon shock absorbent material is not dynamic enough, and that shock or stress absorbency derives from the physiology and biomechanics of the lower extremities as well as from the physics of footgear. The most important modifiable factor in injury prevention was physical conditioning of the lower extremities.

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The 22nd biennial Public Health Conference on Records and Statistics will be held in Washington, DC, July 17–19, 1989. The conference is sponsored by the National Center for Health Statistics and serves as a major national forum for the latest advances in public health statistics.

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