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Effect of Foot Orthoses on Ankle and Foot Injuries in Military Service Recruits: A Randomized Controlled Trial

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Lower extremity injuries are common among military recruits and leads to poor military outcome. Orthotics are shown to reduce injuries in runners. Effect of orthotics on military recruit foot injuries have not been adequately studied. We aimed to assess orthotics' effect on ankle sprains, foot pain, tenderness and injury intensity in military recruits. 610 recruits entered this randomized, non-blinded, single centered controlled trial, 300 recruits were given a semi-rigid orthotic to put in their boots and 310 recruits who were not given anything were assigned as the control group. They were asked about history of foot pain in seven distinct parts of the lower limb and ankle sprains and their severity and were examined regarding tenderness in those foot parts for 2 times: at the beginning and the end of the two-month military trainings. Ankle sprain frequency did not differ significantly in trials (0.27±1.2) compared with controls (0.12±0.55) while ankle tenderness was significantly more common (p=0.02) and heel, foot arc and metatarsal pain and tenderness were significantly less common among trials. Pain induced inability to march or walk was less common in trials (p<0.00). Orthotics reduce foot sole pain and injury intensity and help to reduce pain induced training inability in military recruits. Further studies should assess their effect on ankle and leg pain.

Key words: Foot Orthoses, Ankle Injuries, Foot Injuries, Military Personnel, Pain Measurement.

Lower limb injuries are common among military recruits; stated as high as 16% during a 30 week program in British Royal Marines[1]. These injuries cause loss of training time and costs[2-4] or even discharge of the recruits[5] which lead to poor military outcome[6]. Most of these injuries are due to lower extremity overuse during physical training activities, specially running[7]. That is why runners experience similar injuries[8-10].

Orthotic devices reduce the incidence of foot injuries in runners. They redistribute pressure under the foot, minimize load on muscle and improve biomechanics of the foot[11-14]. Orthotics can control chronic plantar heel pain, plantar fasciitis[15] and Achilles tendon pathologies[16] in runners. On the other hand, in basketball players it has led to pressure increase on fifth metatarsal and maximum ankle inversion angle which may lead to fractures and frequent ankle sprains respectively[17]. Military training can be assumed a

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combination of running and jumping - as in runners and basketball players- plus marching and other martial drills; the foot wear and equipment also differ. Effect of different insoles on foot injuries in soldiers have been studied but materials and designs have been various and so the results[18-20]. Effect of orthotics on stress fracture incidence in military has been shown[21]. Dixon, S et al. declared their effectiveness in impact force reduction in a biomechanical study but required an injury frequency study in military recruits to confirm[22]. To our knowledge, the effect of orthotics on ankle sprains and specific foot part injuries in soldiers has not been assessed.

In this study, we aimed to: (1) assess the effect of foot arch support on ankle sprains and (2) pain and tenderness in different parts of foot in a group of recruits consisting normal, high and low arched feet.

MATERIALS AND METHODS

Study Design

Military service recruits (who are all of male gender in Iran) referred to Shahid Hashemi Nejad garrison for the two-month martial trainings beginning in April 21st 2014 entered this randomized, non-blinded, single centered controlled trial. Those who signed the informed consent were included and examined to find out if they met the exclusion criteria:

1) Rigid flat foot (when foot arch does not appear even while person stands on his toes)
2) The difference between the actual size of the lowers limbs more than 1 cm
3) History of fracture in the lower limbs
4) Being a professional athlete in football, volleyball, basketball or judo, taekwondo or other martial sports
5) Being exempted from marching and martial trainings by physician's order.

Sample Size

According to the Cochran's sample size formula, while α=0.05 and test power, β= 0.2 and P_1=0.27 according Finestone A et al. study (23), n is calculated to be 202 for each group and therefor the sample size will be 404. We chose a sample of 610 recruits (300 trials and 310 controls) to compensate for the predicted 30% miss to follow up (Figure 1).

Intervention and orthoses specifications

We assigned codes to the eligible soldiers and they were put in trial or control group according to table of random numbers. Soldiers in the trial group were given an orthotic arc support according to their boot size to wear inside it while nothing was given to the control group. All the boots dedicated were also new to prevent effect on stress injuries[24]. The semi-rigid orthotic was made of Acrylonitrile Butadiene Styrene by Orthopedy-Fanni-Pishraft Medical Devices Company, Tehran, Iran (http://pishraft-center.ir).The company claims it redistributes pressure under the foot and decreases pain and discomfort in heels and metatarsals. It fits the shape of the foot bed and it has both longitudinal and transverse arches. In size 44-45, the maximum arc height in the plantar surface is 37mm and 23mm in the bottom surface. The thickness varies in different parts, it is as thin as 3mm under the toes. (Figure 2) Soldiers who did not use foot arc support during the study for any reason were excluded.

Soldier's physical activity routine in military service

On average soldiers wear martial boots for 12 hours a day and 6 days a week in the two month period. That included 6 hours of marching, running and other martial trainings plus about 16 hours of stance during night shifts and standing in lines per week.

At the end of the training period soldiers had a three-day camping in the mountains which consisted a six-kilometer long walking uphill with 15kg equipment in backpack. In the mountain they had to run uphill and climb the back of moving trucks and jump out again and perform all the martial skills learnt for about 10 hours per day.

Outcomes

At day 1 soldiers were asked regarding their demographic info, physical activity routine, past history of trauma or any intermittent or persistent pain in any of seven different parts of their lower limbs below the knees: (1) toes (2) foot dorsum (metatarsals) (3) arch of the foot (plantar fascia) (4) ankle (5) bottom of the heels (6) posterior to the heels (7) leg (Tibial shin). These parts were introduced on a picture to all the recruits. History of frequent ankle sprains and their severity categorized as (1) just pain (2) edema or (3) ecchymosis was also taken. Then they were

examined regarding flat foot, cavus and tenderness in any of those seven parts of lower limbs.

At the end of day 60, the two groups were again asked regarding pain history in the seven parts of the lower limbs, number of ankle sprains and their pain severity according to the level of disability it caused: (1) none or not bothering, being unable to (2) march or (3) walk. We once again examined them looking for tenderness in foot parts.

Then we categorized pain and tenderness variables in each foot part as better, no change or worse, by comparing secondary and baseline data in each of the seven foot parts.

Ethics and registry

The study was approved by Baqiyatallah University of Medical Sciences Ethics in Research Committee. It was completely introduced to the soldiers both oral and written in the informed consent. There was no obligation to participate and no penalty was given to participating recruits. The study is also registered in Iranian Registry of Clinical Trials (www.irct.ir); registration number: IRCT2014030916914N1

Statistical analysis

Data were analyzed in SPSS version 16. A $p < 0.05$ was considered to be statistically significant. Data were tested for normality separately in trial and control groups. To compare normally distributed variables between study groups, independent-samples T Test was used. To compare non-normally distributed and ordinal categorical variables Mann-Whitney U test was applied. For other categorical variables chi-square test was administered. In case data in a variable were less than what chi square test required, variable subgroups were merged and ***p*** was stated according to Fischer's Exact Test.

RESULTS

Participants' demographic and physical activity data before the study, are presented in Table1. Most participants are in their early twenties and they had at least a high school diploma. About 20% of the participants had the history of insole use but the insoles had been non-prescribed, soft and only cushioning**.** None of the baseline variables differed significantly between the trial and control groups.

The two groups were compared regarding ankle sprain frequency and intensity (Table 2). In each group 20 recruits had history of frequent ankle sprains but they did not significantly differ neither in frequent sprains nor in intensity at baseline. During the study, sprains were more frequent in trials (0.27±1.2) compared with controls (0.12±0.55) while their intensity and sprains leading to just pain were more common among the control group

Table 1. Demographic Characteristics and Confounding Factors of the population

Group	Trial N=255	ControlN=301	*P*-value
Age(y) (Mean±SD)	23±1.6	23±3.5	0.54
Weight(kg) (Mean±SD)	74±12	74±12	0.45
Height(cm) (Mean±SD)	175±6	175±5	0.20
BMI(kg/m2) (Mean±SD)	23±3	24±3	0.30
Education			0.56
Diploma	14(31)*	85(31)	
Bachelors	26(56)	174(64)	
Masters	6(13)	13(5)	
Walking Time(h/day)			
0-1	86 (34)	111(38.7)	0.25
1-3	110(43.5)	123(42.9)	
3-6	44(17.4)	24(8.4)	
>6	13(5.1)	29(10.1)	
Sport Time (h/week) (Mean±SD)	1.8±3.9	2.6±5.7	0.29
History of Insole Use	53(20.8)	67(22.3)	0.68
Flat Feet	24(9.4)	32(10.6)	0.67
Cavus Feet	17(6.7)	17(5.6)	0.72

* Data are presented as number(%) otherwise stated

Table 2. Ankle Sprains Frequency and Intensity Before and During Study

Group	Trial N=255	Control N=301	***p*-value**
History of Frequent Sprains	20(6.6)*	20(7.8)	0.58
History Sprain Severity			0.81
non	186(72.9)	226(75.1)	
Pain	33(12.9)	22(7.3)	
Edema	22(8.6)	33(11)	
Ecchymosis	14(5.5)	20(6.6)	
Number of Ankle Sprains			
During Study (Mean±SD)	0.27±1.2	0.12±0.55	0.08
Sprain Severity			0.07
non	239(93.7)	263(89.2)	
Pain	0(0)	11(3.7)	
Edema	14(5.5)	18(6.1)	
Ecchymosis	2(0.8)	3(1)	
Site of Painnon	239(93.7)	263(89.2)	0.06
Medial ankle **or**			
Lateral ankle	16(6.3)	32(10.8)	
Site of Edema			0.69
Non	239(93.7)	274(92.9)	
Medial ankle **or**Lateral ankle	16(6.3)	21(7.1)	
Site of Ecchymosis			0.77
non	253(99.2)	292(99)	
Lateral ankle	2(0.8)	3(1)	

* data are presented as number(%) otherwise stated

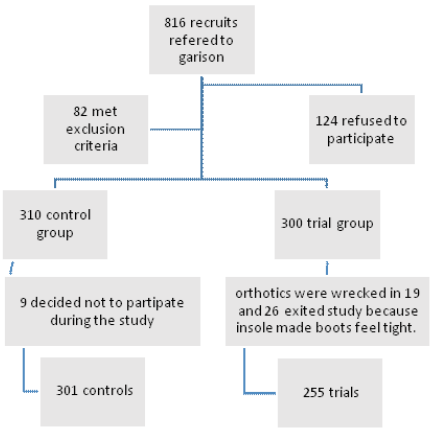

Fig. 1. Flow of participants in the study

Fig. 2. Orthotic arch support

but none of these differences reached statistical significance. Almost all the recruits (trials and controls) who had ankle sprains complained of pain, edema or ecchymosis in lateral ankle.

By comparing pain in different foot parts, 45.5% recruits in the trial group were in the worse category in leg pain compared to 36.2% in the control group**.** Also regarding ankle pain, 8.3% of the trials and 5.3% of the controls fell in worse category. But these differences were not significant. Pains in bottom of heel, back of heel, foot arc and foot dorsum were significantly better in trials.

Leg (tibial shin) and ankle tenderness was again worse among trials than the controls but only the difference in ankle tenderness was significant (***p***=0.02). Tenderness in bottom of heel (***p***=0.007), foot arc (plantar fascia) (***p***=0.001) and foot dorsum (metatarsals) (***p***=0.02) were again significantly worse among controls. No change happened to toe tenderness during the study. (Table 3)

Comparing pain and injury between the

Table 3. Comparison of Pain and Tenderness in Different Foot Parts between the Groups

Group	Trial Group N=255 n(%)	Control Group N=301 n(%)	*p*-value
Pain in:			
Leg			0.07
Better	21(8.2)	22(7.3)	
No change	118(46.3)	170(56.5)	
Worse	116(45.5)	109(36.2)	
Ankle			0.15
Better	7(2.7)	11(3.7)	
No change	227(89.0)	274(91.0)	
Worse	21(8.3)	16(5.3)	
Posterior heel			0.001
Better	16(6.3)	8(2.7)	
No change	215(84.3)	241(80.1)	
Worse	24(9.4)	52(17.3)	
Inferior heel			0.002
Better	13(5.1)	10(3.3)	
No change	227(89.0)	249(82.7)	
Worse	15(5.9)	42(14.0)	
Foot Arc			0.04
Better	11(4.3)	6(2.0)	
No change	237(92.9)	280(93.0)	
Worse	7(2.7)	15(5.0)	
Foot dorsum(metatarsals)			0.004
Better	9(3.5)	6(2.0)	
No change	240(94.1)	272(90.4)	
Worse	6(2.4)	23(7.6)	
Toes			0.57
Better	10(3.9)	9(3.9)	
No change	239(93.7)	291(96.7)	
Worse	6(2.4)	1(0.3)	
Tenderness in:			
Leg			0.14
Better	1(0.4)	0(0.0)	
No change	232(91.0)	280(94.9)	
Worse	22(8.6)	15(5.1)	
Ankle			0.02
Better	1(0.4)	0(0.0)	
No change	232(91.0)	280(94.9)	
worse	22(8.6)	15(5.1)	
Posterior heel			0.16
Better	1(0.4)	2(0.7)	
No change	253(99.2)	286(96.9)	
worse	1(0.4)	7(2.4)	
Inferior heel			0.007
Better	3(1.2)	3(1.0)	
No change	249(97.6)	274(92.9)	
worse	3(1.2)	18(6.1)	
Foot Arc			0.001
Better	7(2.7)	4(1.4)	
No change	248(97.3)	278(94.2)	
worse	0(0.0)	13(4.4)	
Foot dorsum(metatarsals)			0.02
Better	3(1.2)	2(0.7)	
No change	251(98.4)	283(95.9)	
worse	1(0.4)	10(3.4)	

Table 4. Functional pain scale in control and trial groups

Group	Trial N=255	Control N=301	***p***-value
Functional Pain Scale, n(%)			0.00
None or did not bother	172 (67.7)	133 (44.2)	
Prvents marching	77 (30.3)	151 (50.2)	
Prevents walking	5 (2)	17 (5.6)	

two groups according to functional disability proved a significant loss of function among controls compared to trials (***p*** <0.001). (Table 4)

DISCUSSION

The purpose of this study was to assess the effect of a foot orthotic device on ankle sprains and foot injuries. We found that orthotic devices have minimal impact on ankle sprain incidence and intensity in military recruits. On the other hand, orthotics can significantly reduce pain and tenderness in heels, foot arc and metatarsals while they increase tenderness in ankles. Moreover, they can reduce injury intensity as injuries and pain could prevent more recruits in control group than the trial group from marching and running.

In a biomechanical experimental study on fresh frozen cadaver lower extremities, orthotics came out to reduce ankle-subtalar instability while authors propose that if the orthotic is too thick it may lead to inversion sprains[25]. Also in a study on basketball players, use of orthotics lead to an increase in ankle inversion angle[17] these may support why lateral ankle injuries and ankle tenderness were more frequently reported and examined in our study.

Orthotics reduce foot pain and injury by affecting the orientation of foot bones in a way that the pressure is derived more evenly to the foot sole, both bony structure and soft tissue[11, 26]. Besides it alters contact time and maximum force derived to the foot sole[27]. Kitaoka ,H et al. found that orthotics support foot arc and increase its stability[26]. It has been declared that they also decrease tension in plantar aponeurosis[28]. Maybe that is why we observed decrease in foot arc and

bottom of heel pain and tenderness in trials. Also Achilles tendon load which is derived to back of heel is shown to decrease by orthotics use[16].

In many military studies different insoles or footwear have been used which did not prove effective against foot injuries[18-20, 24]. Knapik et al. assigned running shoes and shoes according to foot arch height in US military in three separate studies and the meta-analysis of their work also showed little impact of the shoes and cushioned insoles on foot injuries[19]. Gardner L, et al. used a shock absorbent insole to prevent stress fractures. While their results did not support such an effect for these insoles, they present physical fitness and footwear age as the factor affecting injuries[24]. In our study, participants had baseline physical similarity according to their demographics, walking and sport history. In a study on US Army Band Members, 35 participants used orthotics, three forth of which complained of foot pain. investigators argued that 91% of them rated the width of the shoes worn as poor, also most of the participants had the history of foot pain before use of orthotics and maybe the orthotics have not been prescribed accurately[20]. In one of the few studies where orthotics were used in military recruits, Finestone A et al. observed 11.3% and 16.3% less stress fractures by use of respectively semi rigid and soft orthotics. In another study, orthotics proved effective against tibial and femoral stress fractures only in the presence of high arched, and effective against metatarsal stress fractures in the presence of low arched feet. In our study we did not observe such a trend in individuals with cavus or flat feet[21].

Strengths and Limitations

We had a fairly big population of recruits, almost all of participants were educated and we could convince them to cooperate with precision and a smaller fraction of the participants (about 10%) exited the study than we predicted.

Our study outcome could be more accurate if we could provide a sham-insole for the control group and if we had the participants to fill out a foot health questionnaire at the end of study. Also military service is only for men in Iran, so we had only male participants.

Further studies should assess the effect of orthotics on leg and ankle injuries. As leg pain was the most common complaint among our participants and though it was not significant, the orthotic lead to some increase in leg pain and tenderness. Also a similar study should be performed on army personnel who undergo a more aggressive set of trainings in whom risk of lower extremity injuries is higher.

CONCLUSION

At last, our study presents orthoses as a prevention against foot sole injuries that can prevent intense injuries, which may result in training loss, while it does not seem to have positive impact in prevention of ankle injuries.

Conflict of Interests

This study was supported by a research grant by Orthopedy-Fanni-Pishraft Company, Tehran, Iran. Foot arc supports were provided with a grant equal to 1000 US Dollars for the purpose of this study.

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REFERENCES

1. Riddell DI. Rehabilitation of injured Royal Marine recruits. *Journal of the Royal Naval Medical Service*. 1989 Winter;**75**(3):171-6. PubMed PMID: 2614748.
2. Atlas of injuries in the United States Armed Forces. Military medicine. 1999 Aug;164(8 Suppl):633 pages. PubMed PMID: 10570846.
3. United States. Armed Forces Epidemiological Board. Injury Prevention and Control Work Group. Injuries in the military : a hidden epidemic. Falls Church, Va.: Directorate of Epidemiology and Disease Surveillance; 1996.
4. Jones BH, Canham-Chervak M, Canada S, Mitchener TA, Moore S. Medical surveillance of injuries in the u.s. Military descriptive epidemiology and recommendations for improvement. *American journal of preventive medicine*. 2010; **38**(1 Suppl):S42-60. PubMed PMID: 20117600.
5. Knapik JJ, Canham-Chervak M, Hauret K, Hoedebecke E, Laurin MJ, Cuthie J. Discharges during U.S. Army basic training: injury rates and risk factors. *Military medicine*. 2001; **166**(7):

641-7. PubMed PMID: 11469039.

6. Trone DW, Villasenor A, Macera CA. Negative first-term outcomes associated with lower extremity injury during recruit training among female Marine Corps graduates. *Military medicine*. 2007; **172**(1):83-9. PubMed PMID: 17274273.
7. Trank TV, Ryman DH, Minagawa RY, Trone DW, Shaffer RA. Running mileage, movement mileage, and fitness in male U.S. Navy recruits. Medicine and science in sports and exercise. 2001; **33**(6):1033-8. PubMed PMID: 11404670.
8. Marti B. Benefits and risks of running among women: an epidemiologic study. *International journal of sports medicine*. 1988; **9**(2):92-8. PubMed PMID: 3384527.
9. Koplan JP, Powell KE, Sikes RK, Shirley RW, Campbell CC. An epidemiologic study of the benefits and risks of running. *Jama*. 1982; **17**; **248**(23): 3118-21. PubMed PMID: 7143687.
10. Kindred J, Trubey C, Simons SM. Foot injuries in runners. Current sports medicine reports. 2011; **10**(5):249-54. PubMed PMID: 23531971.
11. Lin TL, Sheen HM, Chung CT, Yang SW, Lin SY, Luo HJ, et al. The effect of removing plugs and adding arch support to foam based insoles on plantar pressures in people with diabetic peripheral neuropathy. *Journal of foot and ankle research*. 2013; **6**(1):29. PubMed PMID: 23895323. Pubmed Central PMCID: 3750449.
12. Mundermann A, Nigg BM, Humble RN, Stefanyshyn DJ. Foot orthotics affect lower extremity kinematics and kinetics during running. *Clinical biomechanics*. 2003;**18**(3):254-62. PubMed PMID: 12620789.
13. Mundermann A, Wakeling JM, Nigg BM, Humble RN, Stefanyshyn DJ. Foot orthoses affect frequency components of muscle activity in the lower extremity. Gait & posture. 2006; **23**(3): 295-302. PubMed PMID: 15946847.
14. Nigg BM, Stergiou P, Cole G, Stefanyshyn D, Mundermann A, Humble N. Effect of shoe inserts on kinematics, center of pressure, and leg joint moments during running. Medicine and science in sports and exercise. 2003; **35**(2): 314-9. PubMed PMID: 12569222.
15. Landorf KB, Menz HB. Plantar heel pain and fasciitis. Clinical evidence. 2008; 2008. *PubMed* PMID: 19450330. Pubmed Central PMCID: 2907928.
16. Sinclair J, Isherwood J, Taylor PJ. Effects of foot orthoses on Achilles tendon load in recreational runners. *Clinical biomechanics*. 2014; **8.** PubMed PMID: 25146855.
17. Yu B, Preston JJ, Queen RM, Byram IR, Hardaker WM, Gross MT, et al. Effects of wearing foot orthosis with medial arch support on the fifth metatarsal loading and ankle inversion angle in selected basketball tasks. The Journal of orthopaedic and sports physical therapy. 2007; **37**(4):186-91. PubMed PMID: 17469671.
18. Knapik JJ, Brosch LC, Venuto M, Swedler DI, Bullock SH, Gaines LS, et al. Effect on injuries of assigning shoes based on foot shape in air force basic training. *American journal of preventive medicine*. 2010; **38**(1 Suppl):S197-211. PubMed PMID: 20117594.
19. Knapik JJ, Trone DW, Tchandja J, Jones BH. Injury-reduction effectiveness of prescribing running shoes on the basis of foot arch height: summary of military investigations. *The Journal of orthopaedic and sports physical therapy.* 2014; **44**(10): 805-12. PubMed PMID: 25155917.
20. Grier TL, Knapik JJ, Swedler D, Jones BH. Footwear in the United States Army Band: injury incidence and risk factors associated with foot pain. *Foot*. 2011; **21**(2):60-5. PubMed PMID: 21236659.
21. Simkin A, Leichter I, Giladi M, Stein M, Milgrom C. Combined effect of foot arch structure and an orthotic device on stress fractures. *Foot & ankle*. 1989; **10**(1):25-9. PubMed PMID: 2788605.
22. Dixon SJ. Influence of a commercially available orthotic device on rearfoot eversion and vertical ground reaction force when running in military footwear. *Military medicine.* 2007; **172**(4): 446-50. PubMed PMID: 17484322.
23. Finestone A, Giladi M, Elad H, Salmon A, Mendelson S, Eldad A, et al. Prevention of stress fractures using custom biomechanical shoe orthoses. *Clinical orthopaedics and related research.* 1999; **360**: 182-90. PubMed PMID: 10101324.
24. Gardner LI, Jr., Dziados JE, Jones BH, Brundage JF, Harris JM, Sullivan R, et al. Prevention of lower extremity stress fractures: a controlled trial of a shock absorbent insole. *American journal of public health.* 1988; **78**(12):1563-7. PubMed PMID: 3056045. Pubmed Central PMCID: 1349736.
25. Tochigi Y. Effect of arch supports on ankle-subtalar complex instability: a biomechanical experimental study. *Foot & ankle international.* 2003; **24**(8):634-9. PubMed PMID: 12956570.
26. Kitaoka HB, Luo ZP, An KN. Analysis of longitudinal arch supports in stabilizing the arch of the foot. *Clinical orthopaedics and related research.* 1997; **341**: 250-6. PubMed PMID: 9269181.
27. A BuJRDN. The impact of different insole arch

supports on the changes of foot loading characteristics. *Journal of Clinical Biomechanics.* 2008; **23**(3): 663.

28. Kogler GF, Solomonidis SE, Paul JP. Biomechanics of longitudinal arch support mechanisms in foot orthoses and their effect on plantar aponeurosis strain. *Clinical biomechanics*. 1996; **11**(5): 243-52. PubMed PMID: 11415628.