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The Role of Biomechanical Shoe Orthoses in Tibial Stress Fracture Prevention

Ingrid Ekenman,* MD, Charles Milgrom,†‡ MD, Aharon Finestone,§ MD, Michal Begin,† MD, Carin Olin,* MD, Toni Arndt,* PhD, and David Burr,‖ PhD

*From the *Department of Orthopaedics, Huddinge University Hospital, Huddinge, Sweden, the †Department of Orthopaedics, Hadassah University Hospital, Ein Kerem, Jerusalem, Israel, the §Department of Orthopaedics, Rabin Medical Center, Beilinson Campus, Petach Tikva, Israel, and the ‖Department of Anatomy, University of Indiana Medical Center, Indianapolis, Indiana*

Background: Biomechanical orthoses have been shown to lower stress fracture incidence in infantry recruits. However, these results may not be applicable to running athletes.
Hypothesis: Training in either running shoes or military boots with custom biomechanical shoe orthoses lessens tibial bone strains and strain rates during walking and running.
Study Design: Randomized controlled laboratory study.
Methods: In vivo strain measurements were made in nine subjects to determine whether the use of biomechanical orthoses lowers tibial strains during both walking and running and whether such lowering depends on the type of shoe worn. Measurements were made during treadmill walking at 5 km/hr and then during serial 2-km treadmill runs at 13 km/hr with running shoes, with and without the orthoses, and during serial 1-km runs with army boots, with and without the orthoses.
Results: When soft or semirigid biomechanical orthoses were worn with boots, the tibial peak-to-peak strains were significantly lowered. Soft orthoses also significantly lowered the tension and compression strain rates when worn with boots. During running, semirigid orthoses significantly increased the compression and tension strain rates when worn with boots.
Conclusions: The use of biomechanical orthoses may be warranted for tibial stress fracture prevention during training in which boots are worn and that mostly involves walking, but they are not warranted for activities that primarily involve running or are performed in running shoes.

Stress fractures are a common problem for participants in both sports and military training.[1,16] They are considered to result from repetitive loading of bone during which high strains or high strain rates occur.[3,4] The ideal strategy for stress fracture prevention is to decrease the magnitude and intensity of these bone strains without affecting the quality of training.

Because of a uniformity of training and a centralized discipline structure, most stress fracture prevention studies have been performed in populations of military recruits rather than among athletes.[7,9,10,14,15,17] In these studies, the use of shock-absorbing shoe inserts has not been found to affect the overall incidence of stress fractures.[10,17] In a prospective randomized trial involving infantry recruits, the use of custom biomechanical shoe orthoses worn within military boots was found to decrease the incidence of stress fractures by 50%.[7] It was hypothesized that the mechanism by which these orthoses lowered the stress fracture incidence was the lowering of bone strains and strain rates. However, infantry recruits do very little running, so the applicability of this finding to sports participants whose principal activity is running and who wear running shoes can be questioned.

In the current study, we hypothesized that training in either running shoes or military boots with custom biomechanical shoe orthoses, either of the semirigid or soft type, lessens tibial bone strains and strain rates during walking and running. If this hypothesis were proved true, it would indicate that use of such orthoses could be effective in

‡ Address correspondence and reprint requests to Charles Milgrom, MD, Department of Orthopaedics, Hadassah University Hospital, Ein Kerem, POB 12000, Jerusalem, Israel.
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lowering the tibial stress fracture incidence in runners and other athletes as well as among infantry recruits.

MATERIALS AND METHODS

Subjects

Nine members of the special forces unit of the Swedish Police volunteered to be subjects for in vivo tibial strain measurements. Their mean age was 32.4 years (range, 26 to 40), mean height was 183.9 cm (range, 178 to 189), and mean weight was 82.8 kg (range, 67 to 96). All subjects received explanations of the goals, risks, and benefits of their participation in the experiment, and all signed informed consent forms. The experimental protocol was approved by the Research Ethical Committee of the Huddinge University Hospital, where the study was conducted, and by the institutional review board at the Indiana University School of Medicine. All subjects were healthy and physically conditioned by their unit's vigorous training regimen, and none had any history of medical problems.

Before the study began, each participant was given a prescription for semirigid and soft composite biomechanical orthoses fabricated from neutral subtalar casts. The semirigid orthosis consisted of a three-quarter length polypropylene module with an integrated neutral heel post and a full-length covering of PPT (open-cell polyurethane), topped with a fabric cover (Langer Biomechanics Group, Inc., Deerfield, New York). The soft biomechanical orthoses (Eshed Advanced Orthopedics Ltd., Bene Brak, Israel) were full-length orthoses with neutral hindfoot posts and were molded from three standard-width layers of polyurethane of different density (upper layer, grade 80; middle layer, grade 60; lower layer, grade 80). One month before the study the participants were also given Nike Air Max running shoes (Nike, Beaverton, Oregon) and Israeli Army infantry boots with double-layer soles (inner layer, 45 Shore A; outer layer, 90 Shore A polyurethane). The weight of the boots was 1600 g for shoe size 45. The study participants were instructed to break in the shoes before the strain gauge measurements. All orthoses and shoes were commercially purchased to avoid conflict of interest.

Before beginning a training protocol, each subject had measurements made of in vivo tibial strain measurements during treadmill walking at a rate of 5 km/hr while wearing the running shoes and army boots with and without the semirigid and soft biomechanical orthoses. Each subject was then asked to complete a training protocol, with only the order of the activities randomly varied between the subjects. Subjects performed successive 2-km runs on a treadmill at a rate of 13 km/hr while wearing the running shoes without orthoses, with the soft biomechanical orthoses, and with the semirigid biomechanical orthoses. Subjects also performed successive 1-km runs on a treadmill at a rate of 13 km/hr while wearing army boots without orthoses, with the soft biomechanical orthoses, and with the semirigid orthoses. Tibial strain recordings were made during the runs at 4 minutes after the beginning of each run. Tibial strain recordings were also made while subjects walked on a treadmill at 5 km/hr immediately before and after each run while wearing the same foot gear as was worn for the run. No rest was allowed between the runs other than the time necessary to complete the baseline treadmill walking measurements and for change of foot gear.

In Vivo Strain Measurements

Sixteen by fifteen millimeter bone staples (3M Health Care, St. Paul, Minnesota) with two MicroMeasurements strain gauges (types EA-06-031DE-350 and EA-06-031EC-350, Measurements Group, Inc., Raleigh, North Carolina) mounted perpendicular to each other on the underside of the staple were used to measure in vivo axial tibial strains. The application of the staple technique to the tibia was validated in vitro before the study.[6] The staples with the strain gauges were inserted during an open surgical procedure into the medial aspect of the middle and distal tibial diaphysis. The raw signals from the strain gauges were amplified by a strain gauge conditioner (Model 2120A, Measurement Group, Inc.). Data were sampled at 1000 Hz and recorded with digital data collection software (Bioware, Kistler, Switzerland). The distal tibial staple was used as a back-up gauge in the event of a technical problem with the midtibia gauge.

Surgical Protocol

Surgical implantation of the staples was performed on an outpatient basis at the Huddinge University Hospital. Surgical implantation was performed in the morning, and the staples were removed the same day after completion of the experimental protocol.

The left leg was prepared and draped and surgical anesthesia was achieved at the site of tibial staple insertion with 2.5 ml of 1% lidocaine and 2.5 ml of 0.5% bupivacaine. A 2.5-cm incision was made over the mid-diaphyseal medial tibial surface. Dissection was carried down to expose the periosteum. A drill guide was used to drill two holes into the cortex to a depth of 4 mm. A specially designed insertion tool was used to insert the staple into the predrilled holes to a depth of 4 mm. Insertion of the distal tibial gauge was similarly performed. The surgical wounds were left open and a gauze dressing was placed loosely over each of the staples. At the end of the experiment, the staples were removed and the skin wounds were closed with two sutures. Prophylactic oral clindamycin was given to the participants at the time of staple insertion and removal.

Data Analysis

Data were processed with a custom-written computer program that took the digitized amplified strain gauge outputs, low-pass filtered them at 5 Hz, and derived the peak-to-peak maximum axial tension and compression strains and the maximum tension and compression strain rates. The maximum strain rates were calculated by scanning every two consecutive data point intervals along the tension and compression strain outputs. Means were calculated for each of the activities on the basis of four consecutive strides. The major outcome variables were the means of the peak-to-peak axial compression and tension strain and maximum compression and tension strain rates for treadmill walking before and after each of the runs and during each of the runs. For each of the individual shoes worn, the major outcome variables were the maximum axial strains and strain rates. To determine whether the mean of each of the major outcomes differed between the type of shoes and orthoses worn, we used the Statistical Analysis System (Cary, North Carolina) general linear models procedure, which performs randomized block analysis for a balanced repeated measures design with one crossover factor. Subjects were treated as a random factor, and activity as a fixed factor.

RESULTS

All of the subjects successfully completed the experimental protocol. There were no malfunctions of the midtibial gauges and only the output from these gauges was used for data analysis. Two of the distal tibial gauges malfunctioned during the experiment. Peak-to-peak axial strains were calculated instead of separate compression and tension strains because of a problem in exact determination of the baseline in two subjects. All subjects returned to

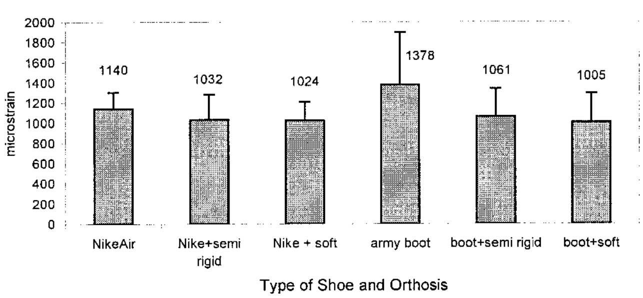

Figure 1. The effect of shoes and orthoses on the peak-to-peak strains during walking. Bars represent standard deviations.

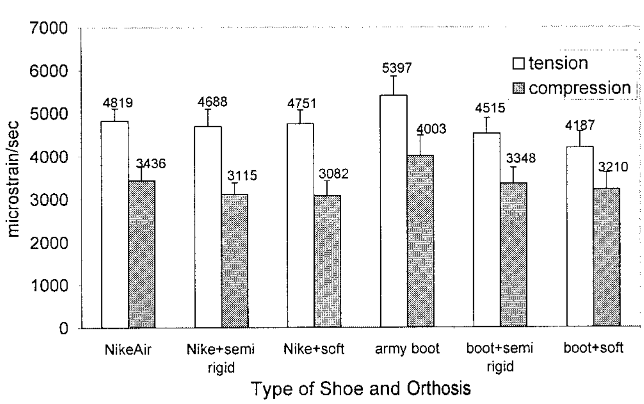

Figure 2. The effect of the type of shoe and orthosis on tibial strain rates during walking. Bars represent standard deviations.

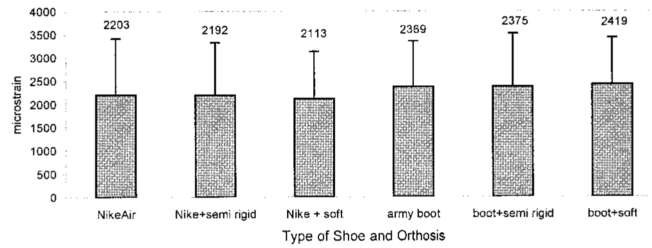

Figure 3. The effect of shoes and orthoses on peak-to-peak strains during running. Bars represent standard deviations.

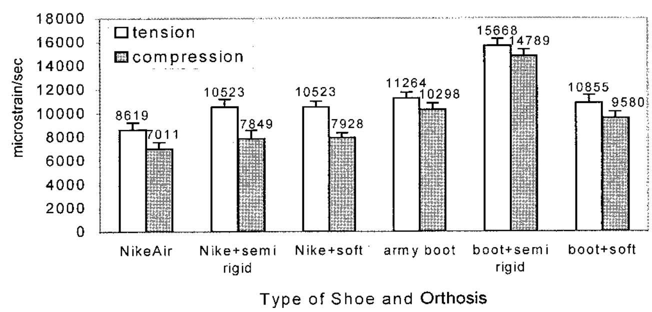

Figure 4. The effect of the type of shoe and orthosis on tibial strain rates during running. Bars represent standard deviations.

their regular training within 10 days of the experiment, although two had residual pain at the site of the distal staple. The pain resolved after 12 weeks in one subject and after 6 months in the other subject. Their blood counts and sedimentation rates were normal. Magnetic resonance imaging studies in both cases showed the presence of soft tissue fibrosis under the surgical scar.

The peak-to-peak strains of the subjects during treadmill walking (before the start of the running protocol) while wearing boots were significantly higher than while wearing running shoes ($P = 0.02$), but there was no significant difference between the shoes and boots when the boots were worn with either of the orthoses (Fig. 1). When either soft or semirigid orthoses were worn with the boots, the peak-to-peak strains were significantly lowered ($P = 0.001$). Soft orthoses significantly lowered the tension strain rates ($P = 0.001$) and compression rates ($P = 0.03$) when worn with boots (Fig. 2). When either soft or semirigid orthoses were worn with the running shoes during treadmill walking, no significant differences were observed in either peak-to-peak strains or strain rates.

The peak-to-peak strains of subjects during treadmill running while wearing boots were not significantly higher than those observed when subjects wore running shoes (Fig. 3). Adding orthoses to either the running shoes or the boots did not significantly affect the peak-to-peak strains. Semirigid orthoses worn within the boots significantly increased the tension strain rates ($P = 0.008$) and compression strain rates ($P = 0.03$) (Fig. 4).

No statistically significant difference was found between the pre- and postrun treadmill walking tension and

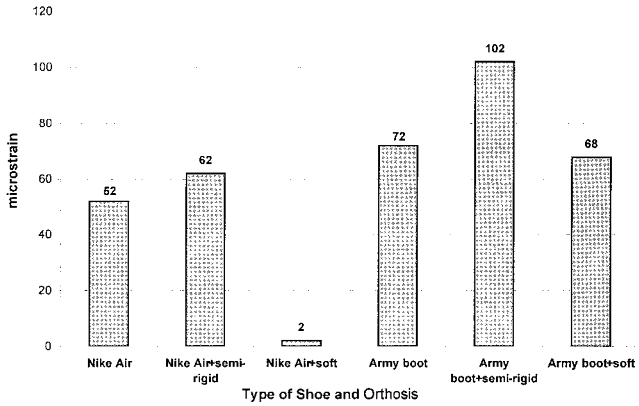

Figure 5. Change in peak-to-peak axial strains after running.

compression strain rates. The peak-to-peak strains during the postrun treadmill walking increased when compared with the prerun treadmill walking for all of the combinations of shoes and orthoses. These increases, however, were not statistically significant (Fig. 5).

DISCUSSION

The concept of using a biomechanical shoe orthosis to limit stress fracture incidence is attractive. It requires only the fabrication of the orthosis and its use by the trainee, without any additional training modification. According to this concept, the biomechanical shoe orthosis lowers the stress fracture incidence by lowering bone strain and strain rates during training or by lowering fatigue-related increases in bone strain and strain rates.[7] The scientific basis for this concept is a previous randomized clinical trial that showed a 50% reduction in stress fracture incidence among infantry recruits who trained with biomechanical orthoses worn within their military boots.[7]

The current study was designed to ascertain if biomechanical orthoses, either of the semirigid or soft type, worn within military boots and running shoes lower the tibial strain and strain rates during both walking and running. Previously, it has been shown that the use of noncustom orthoses, designed for their shock-absorbing ability, do not affect tibial stress fracture incidence.[10,18] Because of the difficulty in recruiting volunteers, previous in vivo human bone strain studies have principally used members of the research team as subjects.[2,11,13] The present study differs in that its subjects were all members of a highly trained special forces unit of the Swedish Police. This population is similar to an athletic population in that they regularly perform demanding physical training. The site of the tibial strain recording in this study corresponds to the most prevalent stress fracture site among both runners and military recruits.

Our findings indicate that while tibial strains and strain rates during treadmill walking are higher in subjects wearing army boots than they are in subjects wearing running shoes, adding biomechanical orthoses to the boots eliminates this difference. Biomechanical shoe orthoses, either of the soft or semirigid type of construction, when worn within military boots lowered the tibial strains; however, only the soft orthoses lowered the compression and tension strain rates. This finding helps to explain the mechanism of action by which the soft biomechanical shoe orthoses lowered stress fracture incidence more than the semirigid biomechanical orthoses in the study by Finestone et al.[7] High strain rates are considered to be a more important factor than high strains in the origin of stress fracture.[17] The biomechanical orthoses used in the study by Finestone et al. were fabricated from neutral subtalar casts. Use of such orthoses may ensure the optimal use of subtalar motion during the phases of walking. The population in the study by Finestone et al. was infantry recruits who wore military boots and whose primary lower extremity activity was walking and marching and not running.

The biomechanics of running are different from those of walking. The sequence of events in the subtalar joint during running varies greatly according to running speed. During sprinting, the heel may be only transiently in contact with the ground surface.[12] The current study showed that the use of biomechanical orthoses with either running shoes or military boots during running did not result in significant changes in the tibial strains. The strain rates also were not significantly affected, except when semirigid orthoses were worn within military boots, which actually increased tension and compression strain rates. These effects seem to indicate that the use of biomechanical shoe orthoses do not have a place in tibial stress fracture prevention in sports in which running is the primary activity. The use of semirigid orthoses in runners may even be contraindicated because of the associated increase in strain rates during running.

Several authors have suggested that during fatiguing activity bone strains may significantly increase and thereby contribute to the development of stress fracture.[5,8] However, little in vivo experimental research has been done to study this hypothesis.[8,13,19] Yoshikawa et al.[20] measured bone strains in the tibias of dogs during fatiguing treadmill running. They documented muscle fatigue by EMG criteria. They found that peak principal strains along the anterior and anterolateral surfaces of the tibia increased by an average of 26% to 35% after muscular fatigue. There was also a change in the strain distribution in the tibia when the muscle became fatigued. They did not report whether any strain changes occurred before the muscle fatigue state was reached. Milgrom et al.[13] reported the in vivo tibial strains of four unconditioned subjects who attempted a 30-km fast-paced desert march. Their tibial tension strains and tension and compression strain rates increased significantly when walking measurements made after the march were compared with walking measurements made before the march. The current study was not designed to be a fatigue protocol. All of the subjects were conditioned trainees who ran a total of 9 km in the experiment, with several short breaks. Small increases in strains were observed in walking measurements made after the runs for all shoe and orthosis combinations, compared with walking measurements made before the runs. These differences, however, were not statistically significant.

A previous study indicated that the incidence of metatarsal stress fractures, but not other types of stress fractures, can be limited by the use of improved shoe shock attenuation.[14] The current study indicates that use of custom biomechanical shoe orthoses, either semirigid or soft, may be warranted for tibial stress fracture prevention during training that mostly involves walking in shoes similar to military boots. Their use for tibial stress fracture prevention during activities that primarily involve running or in which running shoes are worn does not seem to be warranted.

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