Defense R&D Canada
DRDC - Toronto

DRDC Toronto CR 2004-090

INDIVIDUALLY MOLDABLE BOOT INSERTS

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PWGSC Contract No. W7711-027842/001/TOR

on behalf of

DEFENSE R&D CANADA

as represented by

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31 March, 2004

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ABSTRACT

It was previously determined that military personnel would be more comfortable and suffer fewer injuries by using footwear inserts in their combat boots. However, this required several different inserts to be provided. The main question that remained was whether these benefits could be obtained with a single heat moldable insert that could be custom fit to an individual. 163 military personnel were randomly assigned to either a control group where they used their current footwear or an experimental group where they received custom heat moldable inserts. The molded inserts substantially increased the overall comfort of the footwear. They also lead to a decrease in footwear related injuries, particularly soft tissue injuries of the legs. The molded inserts did not affect the pressure under the foot or the muscle activity of the lower leg. It appears that a single, heat moldable insert provided to the military personnel could lead to improved comfort and possibly reduced injuries as well.

RÉSUMÉ

Il a été préalablement déterminé que des semelles insérées dans les bottes de combat assureraient un plus grand confort et une réduction du nombre des blessures pour le personnel militaire. Mais de tels résultats nécessitaient la fourniture de plusieurs semelles différentes. Il restait à savoir si ces avantages pouvaient être obtenus avec une seule semelle thermo-formable qui pourrait être faite sur mesure pour chaque personne. On a sélectionné 163 membres du personnel militaire qu'on a divisés au hasard, entre un groupe témoin utilisant les articles chaussants actuellement en service et un groupe expérimental portant des semelles thermo-formables. Les semelles thermo-formables ont considérablement augmenté le niveau de confort des articles chaussants et réduit le nombre de blessures causées par ces derniers, surtout aux tissus conjonctifs des jambes. Les semelles moulées n'ont eu aucune incidence sur la pression exercée sur la plante des pieds ni sur l'activité musculaire de la partie inférieure de la jambe. Il semblerait donc que la fourniture d'une simple semelle thermo-formable au personnel militaire leur assurerait un confort accru et entraînerait probablement une réduction du nombre de blessures.

EXECUTIVE SUMMARY

Introduction and purpose

Initial results from previous studies with the Department of National Defense were positive suggesting that military personnel will be more comfortable and suffer fewer injuries if they use an insert that is appropriate for their characteristics. The initial studies were performed primarily with varying the material properties of the shoe inserts. The question still remained, however, whether or not inserts that are individually moldable or adjustable to a particular subject are even more beneficial. One type of individually moldable inserts is made of thermoplastic materials that can be heated and formed to the foot shape of the individual. It was speculated that appropriately implemented individually molded inserts could result in even greater improvements in comfort and reductions in injuries and reduce the time required to select the appropriate insert in the military population. ***Thus, the purpose of this study was to determine the influence of individually moldable inserts on comfort and injuries in a military population.***

Methods

Subjects were gathered from a group of military personnel from battalions 1 PPCLI and 3 PPCLI of the Steele Barracks, Edmonton Garrison, Alberta. A total of 163 subjects participated in the study. Participants were randomly assigned to either a control group or a molded insert group. The subjects in the molded insert group received either a regular or extra soft thermoplastic, heat moldable footwear insert that they were to use in their footwear. The control group continued using their current footwear insert. At the initial fitting, all subjects assessed insole comfort. Injury data were then collected over a period from April to December 2003 while the subjects continued to participate in their daily activities while wearing the different inserts. For a subset of individuals in the molded insert group, muscle activation and plantar pressure data were collected during a treadmill march while wearing the molded insert and while wearing the standard issue insert.

Results and Discussion

The use of a heat moldable insert significantly increased the comfort of military personnel by over 4 comfort points. There were no differences in comfort between using a regular or extra soft moldable insert. The injury data has to be interpreted with caution as exact compliance rates are unknown. There was a significant reduction in the overall injuries for the group with the molded inserts. Almost 100% of subjects in the control group incurred an injury while only 88% of subjects with the molded inserts experienced an injury. The greatest reduction occurred in lower extremity soft tissue damage. There was a significant increase in the number of blisters with the molded inserts, which may be due to the surface characteristics of the insole or the reduced space in the boot. The molded inserts did not significantly influence the peak pressures under the foot. They did, however, seem to shift the peak pressure away from the rearfoot and more toward the forefoot. Finally, the molded inserts did not affect lower extremity muscle activity.

SOMMAIRE

Introduction et objectif

Les premiers résultats des études antérieures effectuées en collaboration avec le ministère de la Défense nationale ont permis de conclure de façon positive que l'utilisation de semelles personnalisées assurerait un plus grand confort et une réduction du nombre des blessures pour le personnel militaire. Les premières études portaient essentiellement sur l'utilisation de semelles intérieures faites de matériaux aux propriétés différentes. Il restait donc à savoir si, oui ou non, des semelles formables sur mesure ou ajustables pour un sujet donné, seraient encore plus bénéfiques. Un type de semelles formables sur mesure est constituée de thermoplastiques qui peuvent être chauffés et moulés à la forme du pied de la personne. L'hypothèse a été émise que des semelles moulées sur mesure et correctement insérées pourraient amener une amélioration accrue du confort de la personne et une réduction du nombre des blessures, en plus de réduire le temps nécessaire au choix de la semelle appropriée pour la population militaire. Par conséquent, le but de cette étude était de déterminer l'incidence des semelles formables sur mesure sur le confort et la réduction du nombre des blessures pour la population militaire.

Méthodes

Les sujets ont été sélectionnés parmi les membres du personnel militaire des bataillons 1 PPCLI et 3 PPCLI de la caserne Steele, Garnison d'Edmonton, Alberta. En tout, 163 sujets ont participé à l'étude. Ils ont été assignés, au hasard, soit à un groupe témoin ou au groupe expérimental qui utilisait les semelles formables. Parmi ce dernier groupe, les sujets ont reçu une semelle thermo-formable ordinaire ou une semelle thermo-formable en thermoplastiques extra souples qu'ils devaient insérer dans leurs bottes. Le groupe témoin continuait d'utiliser la semelle actuellement en service. Au premier essayage, tous les sujets ont évalué le confort de la semelle intérieure. Entre avril et décembre 2003, on a recueilli les données relatives aux blessures alors que, les sujets continuaient de porter les différentes semelles et de vaquer à leurs activités quotidiennes. Un sous–groupe du groupe des semelles moulées a été soumis à une marche sur un tapis roulant, avec la semelle moulée, puis avec la semelle actuellement en service, ce qui a permis de recueillir des données relatives à l'activation musculaire et la pression plantaire.

Résultats et discussion

L'utilisation de la semelle thermo-formable a considérablement accru le confort du personnel militaire par plus de 4 points. Aucune différence de confort n'a été relevée entre la semelle thermo-formable ordinaire et la semelle thermo-formable en thermoplastiques extra souples. Les données relatives aux blessures doivent être interprétées avec prudence puisque les taux de conformité exacts sont inconnus. Il y a eu une réduction significative de l'ensemble des blessures parmi le groupe qui portait les semelles moulées. Dans le groupe témoin, près de la totalité (100 %) des sujets ont subi des blessures, alors que pour le groupe équipé de semelles moulées le taux n'est que de 88 %. La réduction la plus importante se rapporte aux blessures associées aux tissus conjonctifs des membres inférieurs. Le port des semelles moulées a causé une augmentation significative du nombre d'ampoules, qui peut s'expliquer par les caractéristiques de la surface de la semelle ou la réduction de l'espace dans la botte. Les semelles moulées n'ont pas eu une incidence importante sur les points de forte pression plantaire. Toutefois, elles ont apparemment déplacé les points de pression de l'arrière du pied vers le devant. Enfin, les semelles moulées n'ont eu aucune incidence sur les activités musculaires des membres inférieurs.

INTRODUCTION

The current study is the fourth phase of a long-term collaboration that began in 1997 between the Human Performance Laboratory and the Defense and Civil Institute of Environmental Medicine, Department of National Defense. The results of the first phase indicated that cases existed where certain groups of individuals with similar characteristics preferred similar footwear inserts. For example, subjects with high plantar foot sensitivity preferred soft and viscous inserts while subjects with low plantar foot sensitivity preferred hard and elastic inserts. Also, individuals with poor skeletal alignment preferred soft and viscous inserts. Based on these results, it was hypothesized that individuals who used footwear appropriate to their characteristics would have increased performance and fewer injuries than individuals who were assigned generic footwear. This hypothesis was evaluated in a second phase

The second phase consisted of on-site testing with 206 military personnel from Edmonton Garrison. Results indicated that all insert conditions were more comfortable than the military issued insert. Furthermore, when subjects were allowed to use an insert they preferred, they were less likely to suffer pain and fractures than if they used the military issued insert. There was no difference in performance (oxygen consumption) between wearing the selected or the issued insert. However, this result must be interpreted with caution due to a limited sample size. An additional result was that comfort could be improved for 90% of the individuals by allowing them to select from a group of only four different inserts.

The positive results from the first two phases suggested that military personnel would suffer fewer injuries if they used an insert that they found comfortable. Since comfort appeared to be a very important discriminator, the third phase of the collaboration was the development of reliable short-term comfort methodology that would correlate to long term comfort. Methods were developed where subjects were able to quantify comfort for different footwear inserts. Using six repeat trials and averaging the ratings from trials 3-6, repeatable and reliable comfort ratings for footwear inserts were obtained within 0.5 comfort points. This testing procedure lasted approximately one hour for four different insert conditions. Furthermore, using this methodology, the short-term comfort ratings were highly correlated to the long-term comfort assessments.

It appears that if military personnel follow the prescribed protocol and evaluate a small number of different inserts that incorporate specific characteristics, they should be able to select an insert that will be appropriate for them. This insert will not only make them more comfortable but could also reduce the incidence of lower extremity injuries. The question still remained, however, whether or not inserts that are individually moldable or adjustable to a particular subject are even more beneficial. One type of individually moldable inserts is made of thermoplastic materials that can be heated and formed to the foot shape of the individual. The initial studies with military personnel were concerned primarily with varying the material properties of the insole. However, recent literature (Mundermann et al., 2003, 2004) indicates that the shape of the insert can have an equal or larger influence. Thus, it is speculated that appropriately implemented individually molded inserts could result in even greater improvements in comfort and reductions in injuries, provide each person with a “custom molded” insert at a fraction of the cost of prescribed custom molded orthotics, reduce the time required to select the appropriate insert and allow the military to issue only one (or possibly a choice of two) standard inserts.

Thus, the purpose of this study was to determine the influence of individually moldable inserts on comfort and injuries in a military population.

LITERATURE REVIEW

Effect of shoe and shoe inserts on injury

It has been suggested that impact forces during running and other activities are associated with the development of injuries and that the improvement of running shoes and surfaces reduce the frequency of impact related injuries (Miller, 1978; Nigg, 1978; McMahon & Greene, 1979; Cavanagh & Lafortune, 1980). In a prospective study, it was found that recruits who trained in basketball shoes had a lower incidence of overuse injuries of the feet than recruits who trained in infantry boots (Finestone et al., 1992; Milgrom et al., 1992). Although it was not measured directly, the effect of improved shock attenuation of vertical impact loads was speculated to account for the reduction of overuse injuries. Shock absorption was suggested as the most important property of shoe inserts (Lewis et al., 1991). The use of a shock absorbing shoe insert was shown to reduce the incidence of soreness in the Achilles tendon, calf and back (Fauno et al., 1993). Viscoelastic shoe inserts reduced back, leg, and foot pain among adults who worked mostly in a standing position (Basford & Smith, 1988; Tooms et al. 1987), and in aerobic dancers (Clark et al., 1989). A recent study showed that the incidence of stress fractures in infantry recruits could be reduced by 16.3% using soft biomechanical orthoses (Finestone et al., 1999). Recently, a concept of minimizing muscle work when using inserts has been proposed. According to this concept, the impact force signal acts as an input variable on the shoe. The shoe sole acts as a first filter, the insert as a second filter, and the plantar surface of the foot as a third filter for this input signal. The filtered information is transferred to the central nervous system and results in a subject specific dynamic response. The subject performs the movement for the task at hand. For a given movement task, the skeleton has a preferred path. If an intervention supports/counteracts the preferred movement path, muscle activity can be reduced/increased (Nigg et al., 1999). Based on this concept, an optimal insert would result in a decrease in muscle activity, improved footwear comfort, and increased performance.

It has been widely reported that shoe inserts are an effective interventional modality for the relief of discomfort to the feet associated with a variety of orthopedic disorders or conditions. A well constructed shoe insert can provide not only shock attenuation, but also appropriate arch support, better fit of the shoe and better control of rearfoot motion (Kilmartin & Wallace, 1994; Gross & Napoli, 1993). Shoe inserts have been shown to be effective in adjusting the biomechanical variables associated with running injuries and reducing the effect of high stresses produced by running activities. Shoe inserts have been successful in the treatment of lower limb osteoarthritis (Keating et al., 1993; Sasaki & Yasuda, 1987). In a study of conservative management of metatarsal and heel pain in the adult foot, D'Ambrosia (1987) suggested that foot orthotic devices may be the most useful treatment of metatarsal and heel pain. It was found necessary to prescribe orthotics in almost all cases of chronic problems to institute permanent relief.

Footwear comfort

Footwear comfort has been shown to be associated with plantar pressure distribution (Chen et al., 1994; Hennig et al., 2000), foot and leg structure (Hawes et al., 1994), foot sensitivity (Mündermann et al., 2001) and overuse injuries (Volpin et al., 1989; Ballas et al., 1997; Richie & Olson 1993). More recently, footwear comfort has been speculated to be associated with biomechanical characteristics such as lower extremity kinematics, kinetics and muscle activity (Nigg et al., 1999; Nigg, 2001), which could in turn influence fatigue and performance. Liu et al. (1998) found that footwear comfort depends on material and shape of inserts in military boots but did not relate footwear comfort of insert conditions to a no insert condition.

Nigg (2001) suggested that if footwear comfort affects muscle activation, wearing comfortable shoes should require lower oxygen consumption than wearing uncomfortable shoes. He was able to show that this was indeed true for a group of ten subjects. Although muscle activity was not measured directly, the implied conclusion was that the muscle activity was greater when wearing the uncomfortable shoes.

Shoe comfort and overuse injuries

Individuals with overuse injuries of the lower limbs were observed to have persistent pain/discomfort before an injury occurs (Volpin et al., 1989; Ballas et al., 1997). The pain/discomfort may serve as a signal to indicate that an injury may be a long-term consequence. A semiflexible insert material was shown to reduce the discomfort in athletes and was suggested to reduce the overuse injury as well (Richie & Olson 1993). Repeated loading of the foot and excessive tension of the plantar fascia have been implicated by several authors as a cause of plantar fasciitis which results in symptomatic heel pain and inflammation (Campbell & Inman, 1974; Newel & Miller, 1977; Kwong et al., 1988). In order to avert such pathological results, it has been proposed that the objective of orthotic intervention is to resist depression of the foot's arch during weight bearing through skeletal support, thereby decreasing tension in the plantar aponeurosis (Campbell & Inman, 1974). When considering shoes, and specifically shoe inserts, increased comfort may simply indicate less risk of overuse injuries. In fact, Mundermann et al. (2001) found that military recruits had reduced lower extremity injuries when allowed to select a shoe insert that they found comfortable.

Shoe inserts and muscle EMG

To date, very few studies have investigated the effect of shoe inserts on muscle activity. The EMG of several lower extremity muscles was compared for a custom molded insert versus no insert on a group of runners with lower extremity pain (Nawozcenski and Ludewig, 1999). In the first half of stance, tibialis anterior muscle activity was increased and biceps femoris activity was reduced with the molded insert. There were large inter-subject variability and it was concluded that EMG responses to inserts were subject specific. Mundermann et al. (submitted) found that the EMG intensity of lower extremity muscles increased with posted and custom molded inserts. They concluded that structural components of shoe inserts affect lower extremity muscle activity and these effects are specific to the phases of running gait.

Molded inserts

Custom molded shoe inserts can be used to attenuate high plantar pressure, to align the foot in a neutral position or to minimize abnormal foot and leg movement (Smith et al., 1986). Custom molded inserts can be made in several ways; e.g. with or without weight bearing and with or without aligning the rearfoot in a "neutral" position (Valmassy, 1996). Although custom molded inserts have been proposed as an effective treatment of running injuries, (Eggold, 1981; D'Ambrosia, 1985) their mechanical effects are not well understood. Recently it has been suggested that molding effects of inserts dominate over other insert aspects such as posting (Mundermann et al., 2003). Thus, molding likely has a large effect on the biomechanics of movement, however, the exact effects are still unknown.

METHODS

General procedure

Subjects were gathered from a group of military personnel from battalions 1 PPCLI and 3 PPCLI of the Steele Barracks, Edmonton Garrison, Alberta. A total of 163 subjects participated in the study. Participants were randomly assigned to either a control group or a molded insert group. At the initial fitting, all subjects assessed insole comfort. Injury data were then collected over a period from April to December 2003 while the subjects continued to participate in their daily activities while wearing the different inserts. For a subset of individuals in the molded insert group, muscle activation and plantar pressure data were collected during a treadmill march while wearing the molded insert and while wearing the standard issue insert.

Shoe inserts

Since the Canadian military does not mandate usage of a single issued footwear insert, the control group consisted of an array of insert types typical of those commonly worn by personnel in the Canadian Army. Those chosen to receive inserts were given a pair of SOLE Custom Footbeds. The footbeds consisted of three layers; an ethyl vinyl acetate (EVA) base that is heat moldable to conform to the shape of the plantar surface of the foot, a poron (open cell urethane) center that acts as a cushioning layer and a perforated polyester weave top layer designed to provide the appropriate friction as well as wick moisture away from the foot. The molded footbeds came in two different cushioning styles: regular and extra soft. Subjects in the molded insert group were able to try on both inserts and select which cushioning style of footbed they would like to receive. Once selected, the inserts were heat molded for each subject according to the manufacturer's specifications. Subjects were then instructed to use the molded inserts in all footwear worn regularly during the testing period.

Subjects

There were 163 military personnel that participated as subjects in this study (2 female; 161 male). The average height, mass and age are listed in Table 1. Subjects were informed of the testing procedure and signed an informed written consent prior to participation. Individuals were randomly chosen to join either the molded or control insert groups. All subjects participated in regular military training duties during the investigation. Because of the duration of the study, some participants were in active duty overseas and/or worked in forest fire fighting during the testing period. As such, the range of physical activity amongst the subjects was highly variable and there was no way to control this aspect between the two groups.

Table 1. Mean height, mass and age of subjects. Standard error is reported in brackets.

	Control Group n=68	**Molded Group n=94**
Height [cm]	175.7 (1.72)	178.2 (0.82)
Mass [kg]	84.0 (1.40)	83.1 (1.13)
Age [yrs]	28.4 (0.65)	29.2 (0.80)

Comfort

Insert comfort was assessed at the initial fitting. Subjects were required to walk in their footwear and then provide a comfort rating for the insert using a 15cm Visual Analog Scale (VAS) (Mundermann et al., 2002). The VAS was anchored on the left side with the statement "not comfortable at all" and on the right side with the statement "most comfortable condition imaginable". Subjects were asked to place a vertical mark along the scale line representing their opinion of relative foot comfort for the particular condition they were assessing. The subjects in the molded insert group provided performed repeat comfort ratings using the standard issue insert as a baseline control. The final comfort measure was used as the stable/repeatable comfort assessment of the insert condition (Mundermann et al., 2002).

Injuries

All subjects were asked to record physical activity and injury or pain in a standardized personal logbook, which was provided by the investigators. Epidemiological data pertaining to injuries of the lower limbs was also gathered using an exit questionnaire (see appendix A) and by accessing military medical records. An injury was defined to be any type of pain, or damage occurring in the lower limbs or lower back during the period of April to December of 2003. Head Surgeon Dr. Peter Clifford, of the Edmonton Garrison Medical Center arranged to tally injury frequency and type for both the insert condition groups, in order to sanitize subject identities from the injury data and ensure patient confidentiality. Injuries were compared on a per subject basis for each group. Injury frequency was compared for specific injury modalities and total injuries.

Plantar Pressure

For a subset of nine individuals in the molded insert group, in-shoe plantar pressure data were collected during a treadmill march while wearing the molded insert and while wearing the standard issue insert. These data were collected approximately 3 months after the subjects received the molded inserts to ensure that the subjects were accustomed to the new inserts. Pressure was measured on the plantar surface of the right foot during a 3 mph treadmill march while wearing the molded insert and while wearing the issued insert. Pressure was measured at 100 Hz using Pedar insoles with 99 sensors of approximately 1 square cm. Peak pressures averaged for ~10 steps and compared between the molded and issued insert for the forefoot and rearfoot.

Electromyography

Muscle activation was assessed on a subgroup of 12 subjects during a 3 mph treadmill march. Electromyography (EMG) was collected while subjects walked with the molded insert and the issued insert. Muscular activity was collected on three muscles of the right leg: soleus, tibialis anterior and gastrocnemius medialis. Prior to applying the Ag/AgCl bipolar electrodes (novotrode 20; inter-electrode spacing 2.2 cm) the skin was prepared by shaving any hair over the contact area and cleaning with isopropyl alcohol wipes to reduce the electrical impedance between skin and electrode. Leads connecting the electrodes to the collection unit were secured using adhesive bandages; the collection unit was secured to the handle bar of the treadmill in use. The data were sampled at 2000 Hz. EMG data were collected and averaged for ~10 steps (30 seconds). Activation intensity was determined using a Root Mean Square analysis.

Statistics

Average comfort was analyzed using paired t-tests within the molded group and unpaired t-tests across the two groups. Injury rates were analyzed using a Chi-square test. Peak pressure and electromyography data were compared with paired t-tests. In all situations, the level of significance was chosen as α=0.05.

RESULTS AND DISCUSSION

Comfort Assessment

Of the 94 subjects in the molded group, 48% (45) selected the regular insert and 52% (49) selected the extra soft insert. The molded inserts were significantly more comfortable than the control condition for the insert group (Figure 1). The average increase in comfort rating was 4.2 comfort points with the molded inserts. The increase in comfort rating was independent of which molded insert (the regular or the extra soft) was chosen as there was no significant difference between the comfort ratings for the two different molded inserts (Figure 2).

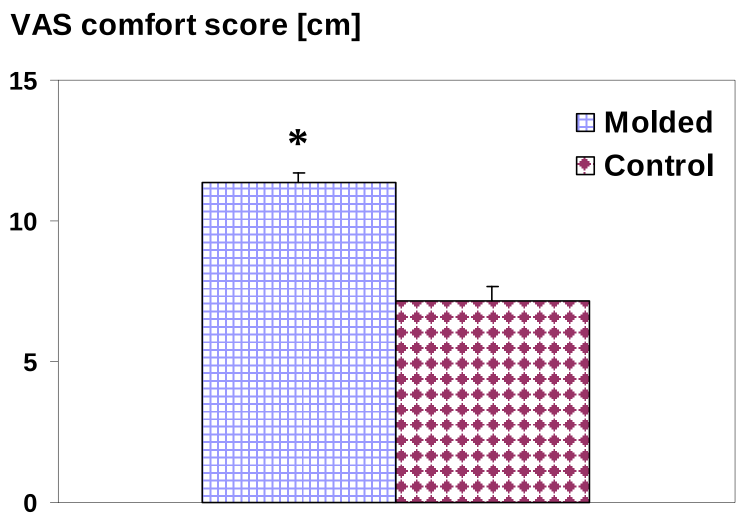

Figure 1. Average comfort results for the molded and control inserts within the molded group. * indicates a significant difference from the control group.

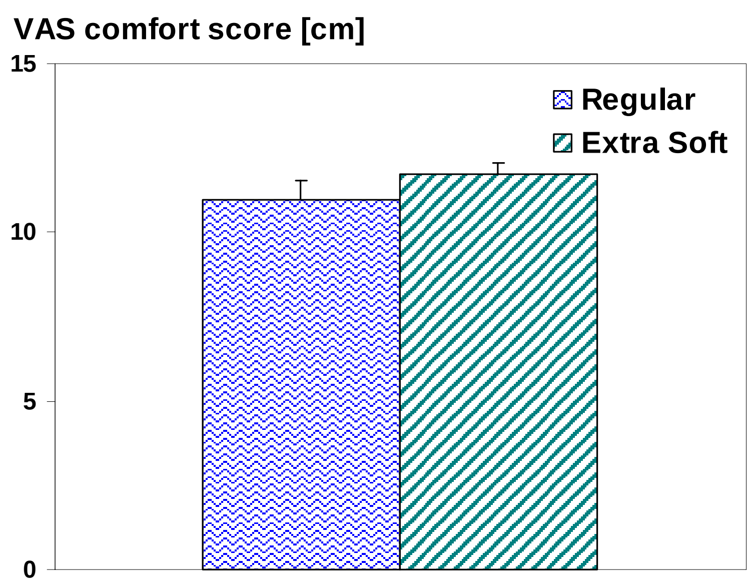

Figure 2. Average comfort results for the individuals within the molded insert group who selected either the regular or extra soft SOLE insert.

When comparing the comfort ratings between the groups, the average comfort rating for the molded insert was 11.4 comfort points while the average rating for the control condition was 10.4 comfort points (Figure 3). These differences were not significantly different, however, they were very close to the level of significance chosen (p=0.054). The subjects in the control group tended to rate the control condition higher than the subjects in the molded insert group. This may be the result of not having any other condition to compare to. Mundermann et al., 2002 suggest using a baseline condition for all comparisons, however, this was not practical in this study.

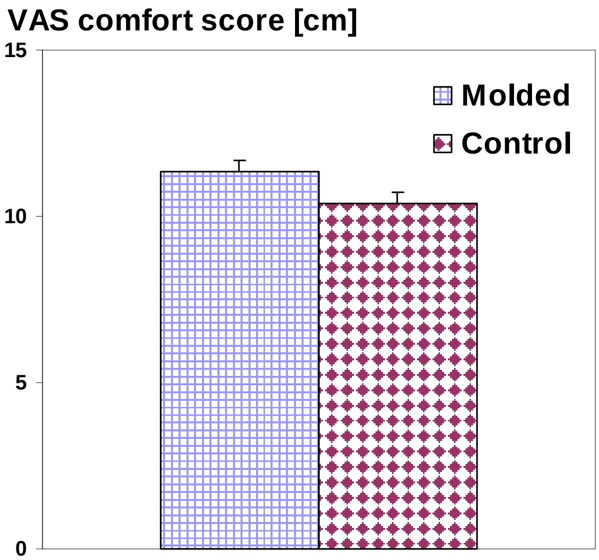

Figure 3. Average comfort assessment of the conditions worn for the injury assessment protocol.

Injury Frequency

The actual compliance of the individuals in wearing the experimental molded insert is unknown. This information was to be recorded in the logbooks. However, virtually all of the subjects stopped recording the data at some point during the study. Therefore, the injury data presented are from exit questionnaires and medical records and must be interpreted with caution.

The control group experienced 68 injuries and the molded group experienced 83 injuries (Table 2). However, the molded insole group experienced a significantly lower percentage of injuries per person (88.3%) compared to the control group (98.6%). The relative percentage of blisters increased from 8.7% in the control group to 20.2% in the molded insert group. This was found to be a significant increase and could be due to the surface properties of the insert or the reduced space in the footwear. There was a significant decrease in soft tissue damage from 36.2% to 17.0% for the molded insert group. There was no significant difference in either back or lower limb pain between the two groups.

Table 2. Injury frequency and modality for both the control and molded insert groups.

Injury Modality	Control N=69		Molded n=94	
	#	%	#	%
Total Injuries *	**68**	**98.6**	**83**	**88.3**
Blisters *	6	8.7	19	20.2
soft tissue damage *	25	36.2	16	17.0
back pain	10	14.5	8	8.5
lower limb pain	18	26.1	31	33.0

* indicates a significant difference between the two groups.

The injury data are very similar to the previous study conducted on the military population with the shaped inserts. In that study, the insert reduced the injury rates for all specific pain and fractures, however, the only significant reduction was in the injuries that occurred at the feet. Another similar result was that the insert increased the incidence of blisters. Thus, it appears that providing an insert that improves comfort can significantly reduce the overall incidence of injury (provided that the number of blisters can be controlled).

Plantar Pressure

The molded insert condition showed a trend towards a decrease in peak pressures in the rearfoot and an increase in the forefoot as compared to the control condition. No significant differences were found. Figure 4 shows a graph of the peak pressure measurements for both insert conditions in the forefoot and rearfoot.

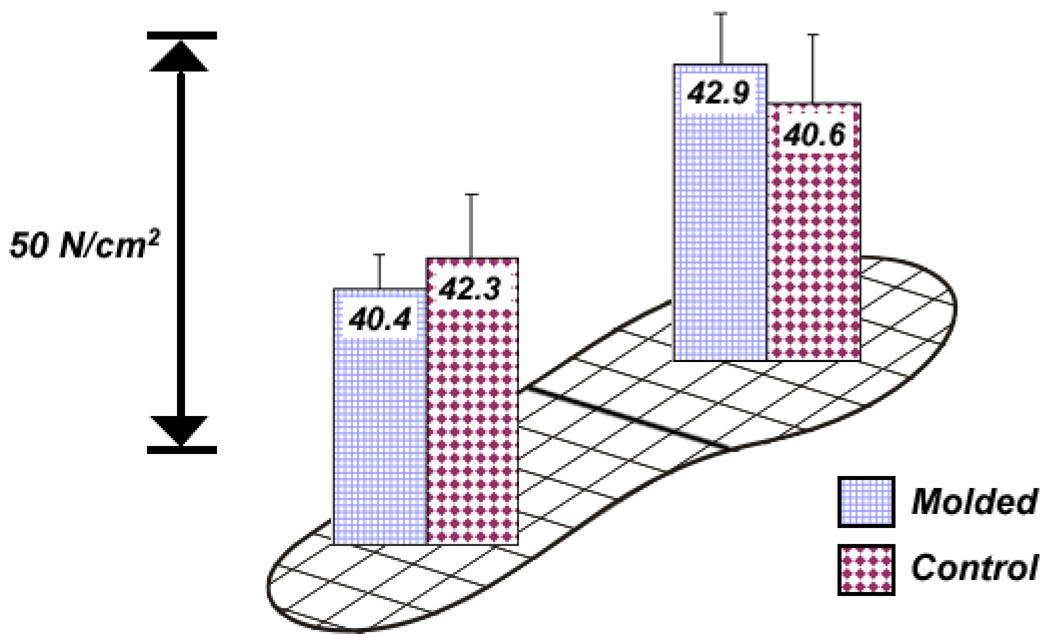

Figure 4. Peak Plantar Pressure (N/cm^2) during a 3mph treadmill march. Peak Pressures were averaged for ~10 step cycles for 9 male subjects. No significant differences were found between the insert conditions.

It was speculated that on average, peak pressure would decrease in the molded insert. The molded footbed condition should have been able to distribute plantar pressure over a greater surface area of the foot, which could possibly result in a decrease in peak pressure. However, this was not found. Interestingly, a shift was observed in peak pressure from the rear foot to the forefoot for subjects while wearing the molded insert condition. It appears that the molded inserts simply manipulated the location of the peak pressures. It is unknown how this shift in pressure distribution affected the observed injury tallies, but it may be one reason for the increased number of blisters with the molded insert condition.

Electromyography

Boot inserts seemed to have little to no effect on muscle activation in the ankle plantar and dorsi-flexor muscles. Figure 5 shows a summary graph for the mean RMS values in 12 male subjects, during a stride cycle for a 3mph treadmill march. Tibialis anterior showed a trend of increased activation in the molded condition as compared to the control, but this difference was not found to be statistically significant. It is speculated that the increase in TA activation in the molded condition may have been a result of accelerating an increased boot mass through swing phase.

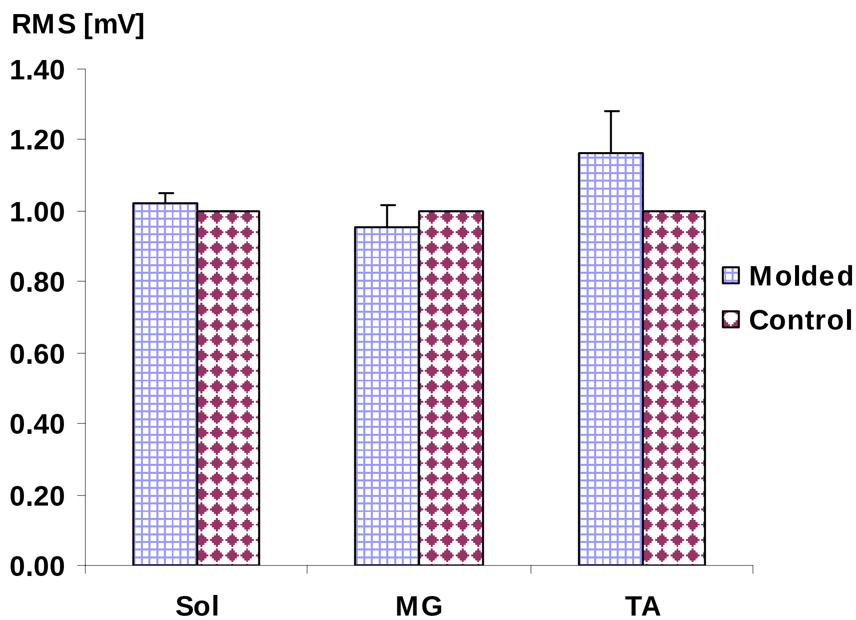

Figure 5. EMG RMS values (mV) averaged over a single step cycle. RMS values were averaged for ~10 steps for 12 male subjects. EMG was recorded during a 3 mph treadmill march. No significant differences were found between the insert conditions.

In this investigation, we did not find that a more comfortable insert resulted in any statistically relevant change in muscle activation. These results are similar to the data found in the third phase of this study where changes in inserts produced no consistent effects with respect to muscle activity. Changes in muscle activity were expected when the inserts attempted to change the path of motion. However, these changes may have been small providing only small differences in functional responses. Thus, the conclusion from the previous studies that assessment of EMG activity may not be appropriate for assessing the functionality of inserts/orthotics/shoes with small changes is further supported here.

Acceptability Ratings

To gain insight into the overall subject opinion of the molded insole, an assessment questionnaire was given at the conclusion of the investigation. This questionnaire rated the acceptability of both insert conditions over a number of desirable traits (Appendix B).

The poll was taken by a focus group of 56 soldiers. Thirty four of the polled subjects were of the molded testing group, and most were able to give acceptability ratings on both types of inserts. The remaining 22 subjects only reported on the acceptability of the control inserts. Figure 6 reports the mean acceptability scores given by all subjects of the focus group. The acceptability scores are based on an 11 point scale. An 11 signifies a completely acceptable insert condition and a zero represents total unacceptability.

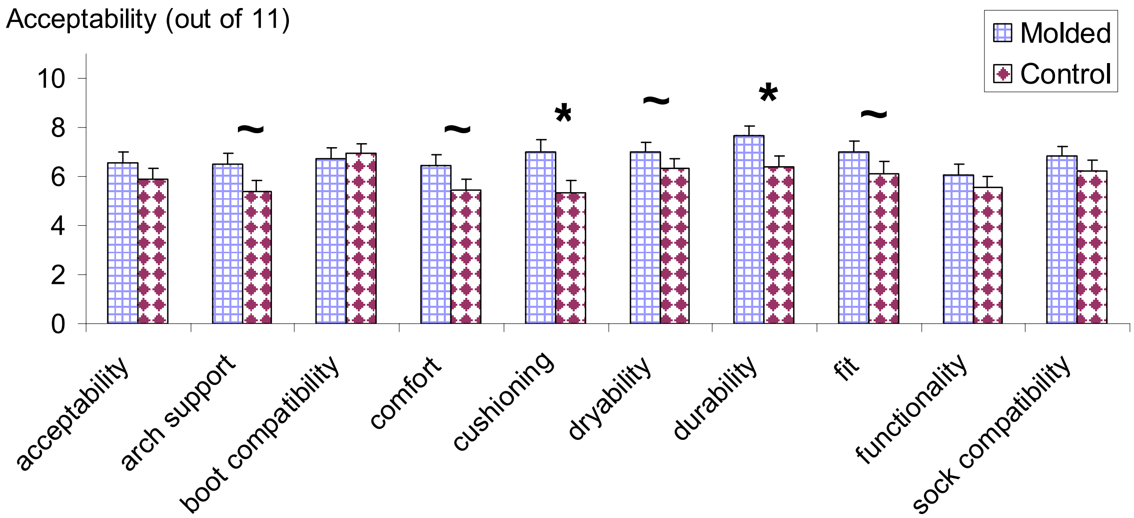

Figure 6. Acceptability ratings for the molded (n=34) and control (n=46) inserts as rated by a subject focus group. Acceptability was rated on an 11 point scale (* = p value < 0.05. ~ = p value <0 .1).

The molded insert showed a trend towards higher acceptability in nine of the ten insert qualities polled. Boot compatibility was the only insert characteristic where the molded condition showed a trend towards lower acceptability. Of the remaining nine footbed traits, cushioning and durability acceptability were found to be significantly higher in the molded insert condition. Arch support, comfort, dryability and fit showed strong trends towards greater acceptability in the molded insert (p value < 0.1).

With ratings of all ten insert characteristics averaged into an overall mean acceptability score, the molded insert was found to be significantly higher than the control condition (figure 7). In summary, the molded insert condition was rated as a more acceptable footbed, for a variety of insert characteristics, compared to the control condition, by a focus group of 56 soldiers.

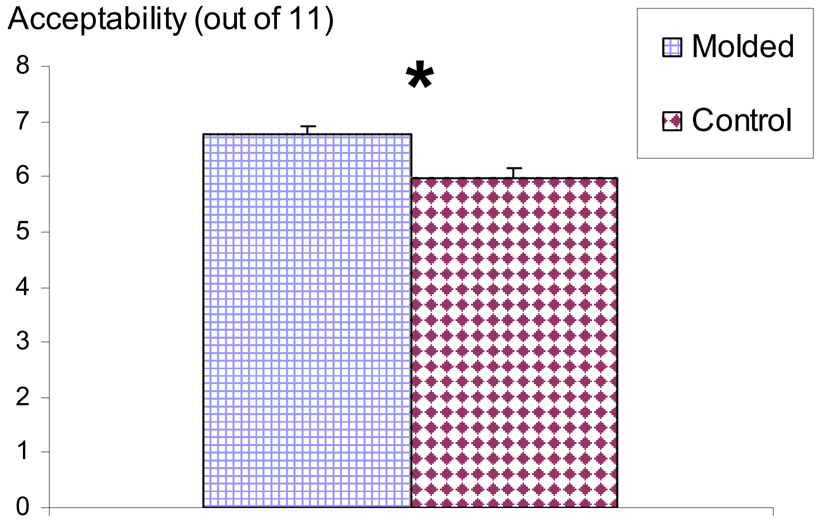

Figure 7. Overall mean acceptability ratings for the molded and control inserts as rated by a subject focus group. Acceptability is rated on an 11 point scale. The molded footbed was found to have a significantly higher acceptability rating than the control (* = p value < 0.05).

The above findings were based on poll results from the entire focus group. This included information from soldiers in the control group who never tried a molded footbed. In our focus group, there was a group of 27 subjects that were able to give acceptability ratings on both insert types. Figure 8 shows the acceptability ratings from the subjects of the molded group that rated both insert conditions.

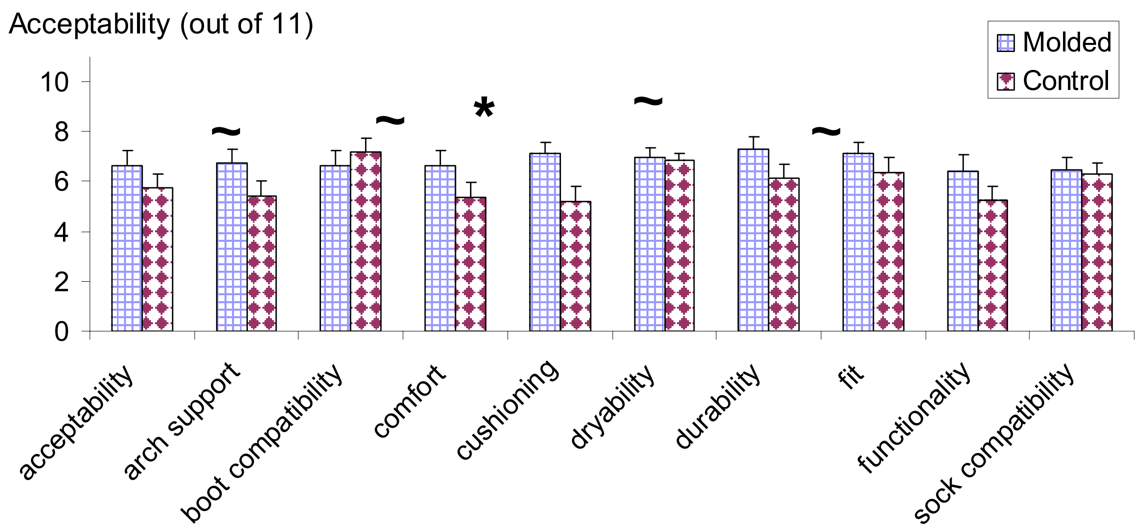

Figure 8. Acceptability ratings for the molded and control inserts as rated by subjects who gave opinions on both footbed types (n=27). Acceptability was rated on an 11 point scale (* = p value < 0.05. ~ = p value <0 .1).

When compared directly by subjects who had used both footbeds, the molded insert tended to rate with greater acceptability in 9 out of 10 of the characteristics polled. Boot compatibility again was the lone characteristic that tended towards lower acceptability for the molded footbed. Cushioning was significantly more acceptable in the molded insert as compared to the control. Arch support, comfort, durability and functionality showed strong trends towards higher acceptability in the molded condition (p value < 0.1).

In summary, cushioning was the lone characteristic found to be significantly more acceptable in the molded insert as compared to the control. This is not surprising considering the Sole footbeds are considerably thicker than the standard issue insoles that come in the combat boots. Boot compatibility showed a trend towards lower acceptance in the molded insert type. This was a concern from the onset of the study because the sizing in the Sole insert is much less varied than that available in military combat boots. There was an attempt to trim oversized inserts to “custom fit” each footbed to a specific boot. Nevertheless, boot compatibility remained an issue in the opinion of those polled. Sizing inserts specifically for boot fit should be addressed directly when considering wide spread use of these insoles for a military setting. Overall, the molded footbed was found to be generally more acceptable for use than the standard issue insert in the opinion of a focus group of soldier subjects.

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APPENDIX A

COMBAT BOOT INSERT TRIAL
INJURY QUESTIONNAIRE

Subject surname:		First name:	
Rank:		Service #:	

Blue Log Books

- ☐ I lost my logbook
- ☐ I still have my logbook and it is enclosed with this questionnaire
- ☐ Other (please specify): ____

Inserts

If you did not receive a pair of inserts during this study, please skip this section and fill out the injury information below.

If you did receive a pair of inserts, did how often did you wear them between April and October 2003?

☐ SELDOM (FOR A FEW DAYS) ☐ PARTIALLY (FOR THE FIRST FEW WEEKS)

☐ REGULARLY (FOR THE FIRST FEW MONTHS) ☐ REGULARLY (FOR THE ENTIRE TIME PERIOD)

Injury Information

For the evaluation of all collected data it is necessary to get information about any lower extremity injury (lower back, knees, legs, feet, etc.) you have had in the time period from April – October 2003.

Please list any injuries, pain, or discomfort you have experienced in your lower extremities during the past four months: (feel free to continue on the back of this sheet if needed).

Part of Body (ex. foot, knee, lower back, etc.)	Frequency of Injury	Description of Injury or Pain

DOCUMENT CONTROL DATA SHEET

1a. PERFORMING AGENCY Human Performance Laboratory, The University of Calgary, 2500 University Drive N.W., Calgary, Alberta, Canada T2N 1N4	2. SECURITY CLASSIFICATION UNCLASSIFIED -
1b. PUBLISHING AGENCY DRDC Toronto	

3. TITLE

(U) Individually moldable boot inserts

4. AUTHORS

Darren J. Stefanyshyn, Brady Anderson, Benno M. Nigg

5. DATE OF PUBLICATION March 31 , 2004	6. NO. OF PAGES 18

7. DESCRIPTIVE NOTES

8. SPONSORING/MONITORING/CONTRACTING/TASKING AGENCY

Sponsoring Agency:

Monitoring Agency:

Contracting Agency : DRDC Toronto

Tasking Agency:

9. ORIGINATORS DOCUMENT NO. Contract Report CR 2004-090	10. CONTRACT GRANT AND/OR PROJECT NO. 12CK01	11. OTHER DOCUMENT NOS.

12. DOCUMENT RELEASABILITY

Unlimited distribution

13. DOCUMENT ANNOUNCEMENT

Unlimited announcement

14. ABSTRACT

(U) It was previously determined that military personnel would be more comfortable and suffer fewer injuries by using footwear inserts in their combat boots. However, this required several different inserts to be provided. The main question that remained was whether these benefits could be obtained with a single heat moldable insert that could be custom fit to an individual. 163 military personnel were randomly assigned to either a control group where they used their current footwear or an experimental group where they received custom heat moldable inserts. The molded inserts substantially increased the overall comfort of the footwear. They also lead to a decrease in footwear related injuries, particularly soft tissue injuries of the legs. The molded inserts did not affect the pressure under the foot or the muscle activity of the lower leg. It appears that a single, heat moldable insert provided to the military personnel could lead to improved comfort and possibly reduced injuries as well.

(U) Il a été préalablement déterminé que des semelles insérées dans les bottes de combat assureraient un plus grand confort et une réduction du nombre des blessures pour le personnel militaire. Mais de tels résultats nécessitaient la fourniture de plusieurs semelles différentes. Il restait à savoir si ces avantages pouvaient être obtenus avec une seule semelle thermo-formable qui pourrait être faite sur mesure pour chaque personne. On a sélectionné 163 membres du personnel militaire qu'on a divisés au hasard, entre un groupe témoin utilisant les articles chaussants actuellement en service et un groupe expérimental portant des semelles thermo-formables. Les semelles thermo-formables ont considérablement augmenté le niveau de confort des articles chaussants et réduit le nombre de blessures causées par ces derniers, surtout aux tissus conjonctifs des jambes. Les semelles moulées n'ont eu aucune incidence sur la pression exercée sur la plante des pieds ni sur l'activité musculaire de la partie inférieure de la jambe. Il semblerait donc que la fourniture d'une simple semelle thermo-formable au personnel militaire leur assurerait un confort accru et entraînerait probablement une réduction du nombre de blessures.

15. KEYWORDS, DESCRIPTORS or IDENTIFIERS

(U) Military footwear, moldable inserts, comfort ratings, injuries