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dated 30 Nov 2011

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Introduction

The primary goal of the Phase I project was to demonstrate the feasibility of this novel approach to an insole device that will reduce injury and enhance ambulatory performance using advanced composites. The overall goal for this multi-phase SBIR project was to develop, prototype, validate, field-test, and deploy the envisioned next-generation boot for use by the Army, other DOD components, and key markets in the government and civilian sectors.

The challenge was to find an innovative solution that will decrease the risk of musculoskeletal overuse injuries and increase ambulatory performance by reducing loading rates while increasing energy storage and energy return. Advanced lightweight composite materials have proven effective in protecting vehicles and soldiers as shielding and as personal body armor. These materials may also prove extremely valuable if used via an innovative design in orthotics for military footwear. The next-generation orthotics can be engineered to provide significant foot protection while enhancing ambulatory performance.

The primary objectives of the Phase I project were to demonstrate the feasibility that the Kingetics orthotic can (a) be produced by a commercial composites manufacturing process and (b) provide a significant decrease in the risk of musculoskeletal overuse injuries while reducing ambulatory energy consumption. A detailed summary of the technical objectives, as principal tasks for Phase I, is given below:

1) Create multiple concept designs for the orthotic, based on Kingetics' patent-pending technology and on performance estimations calculated from material properties, lever/pivot dimensions and locations, geometry, etc.
2) Select two promising design concepts and produce multiple prototype orthotics via a consistent and well controlled fabrication process. This will test production feasibility and provide orthotic prototypes for performance evaluation.
3) Create concept designs and computer generated simulations of a synergistic boot housing that will combine with the orthotic to provide (a) additional mechanical advantage and (2) > 10% decrease in the outsole and midsole weight of the current combat boot.
4) Evaluate the orthotics in relation to various performance criteria, as follows:
    4.1) Apply the ASTM F2412-05 puncture test and demonstrate that the prototype orthotics outperform the related puncture standard (ASTM F2413-05)
    4.2) Apply biomechanical analysis to the orthotic concept designs created in Task.1 to demonstrate that one or more of these designs is predicted to reduce injury risk by
    >10%.

    - 4.3) Demonstrate a significant reduction in oxygen consumption based on predictions from shoe weight and calculated levels of energy return from the orthotic.
    - 4.4) Apply biomechanical analysis to estimate comfort ratings and demonstrate an increase of 10% when compared to traditional combat boots.
    - 4.5) Demonstrate fire retardancy of the prototype orthotics by applying the UL 94 flammability test.

5) Make an initial estimate of the useful life expectancy of the orthotic based on materials properties documented in the literature, and estimate manufacturing costs based on existing commercial processes.
6) Submit a final, summary report that documents what has been done, what is yet to be accomplished, and how we are prepared to move through the Phase I Option, into Phase II activities and beyond, culminating in a product that supports our Warfighters.

PHASE II, if funded, will produce prototypes with systematic design variations which will be evaluated with multiple biomechanical and mechanical tests. Results from these studies will be used to revise and optimize the orthotic. Specific biomechanical testing will include: 1) muscle activation (EMG); 2) kinetics & kinematics (joint angles, angular displacements, and moments); 3) pressure distribution; 4) oxygen consumption (VO2); 5) impulse; 6) comfort; and 7) impact testing. Revised prototypes will be further assessed using biomechanical methods for validation and functional effectiveness, and a final design will be identified and built. A prospective study will also be executed to add credibility to the reduction of injury risk claims. Another focus of Phase II will be optimization of the component integration and fabrication methods to ensure that the orthotics can be manufactured and integrated into a suitable boot housing via robust, cost-effective, commercially viable processes. Sourcing solutions for mass production will also be validated in this phase.

Kingetics is also well-positioned to pursue Phase III collaboration, if funded, with one or more key prime contractors when we successfully complete the Phase I and Phase II work on this project.

PHASE III, if funded, will validate and field test applications and further develop synergistic orthotic boot coverings (uppers and soles). The advanced orthotic system and accompanying boot and shoe systems will be integrated into the current service uniforms for the United States military and paramilitary entities, as well as Homeland Security, fire and police departments, and NASA. A prime defense contractor will be identified to manufacture the new generation of military boot and enable their rapid deployment. The commercial applications will continue with incorporation of orthotic technology in prosthetics, braces, and crutch systems used for the treatment of neurologic and diabetic wounds by the Veterans Administration and general public medical practitioners.

Body: Discussion of Specific Task Accomplishments

Task 1; Create and Evaluate Multiple Concept Designs:

The two specific orthotic design concepts, the Sport model and the Safety model, were evaluated and selected for initial testing. Additional evaluations of the two models resulted in a decision to create an orthotic composite using a different material (Spectra®) to confirm that the previously selected materials (Kevlar and carbon fiber) were the best possible choices.

Task 2; Select Orthotic Designs and Manufacture Prototypes:

Two designs, the Sport and the Safety models, were selected for testing and evaluation. Sufficient quantities the models of each orthotic type were manufactured for Phase I activities. The production processes and procedures for both models are fully documented. In addition to the original materials, three samples of Spectra® composite material were subjected to puncture resistance testing and the report of testing is at Appendix D. The additional material, Spectra®, rated lower in puncture resistance than the current composite material used in the Kingetics orthotics. Spectra®'s performance, however, was significant enough to retain the Spectra® composite as a material of interest in future testing, if funded.

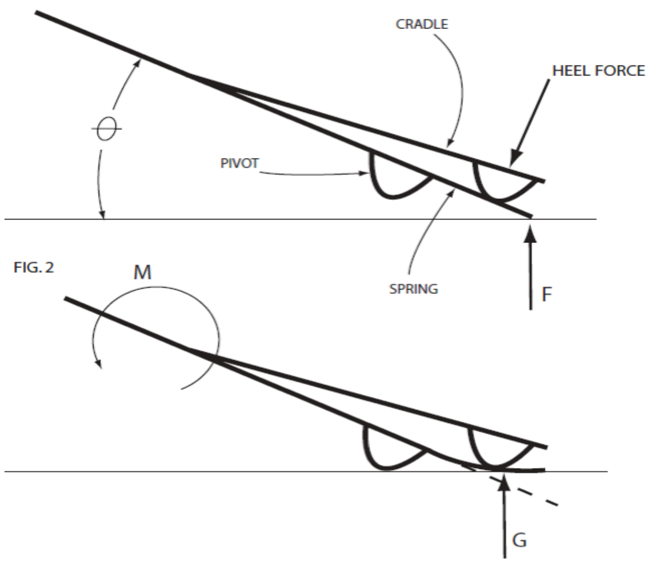
Task 3; Design Synergistic Boot Housings that Add Mechanical Advantage and Reduce Weight:

Kingetics, i-generator, and Crary Shoes had several discussions on different assembly methods based on traditional shoemaking techniques. Based on the discussions and additional sample materials that included our prototype orthotic, Crary Shoes created a prototype boot and provided the prototype boot to Kingetics for evaluation. The prototype boot, the prototype orthotic, and information from the discussions were used by i-generator to complete a set of conceptual drawings, which have also been provided to Kingetics. Pictures of the prototype boot may be found at Appendix A-2. The conceptual drawings may be found at Appendix A-1.

The current boot prototype mechanically assisted the function of the Kingetics orthotic when tested on rugged, mountainous trails. After being tested, it was determined that the boot design could be slightly improved by stretching the toebox to increase the ball width and by opening up the posterior heel counter to accommodate heel movement. These changes were discussed with Crary Shoes, and it was suggested that a good solution may be to create a heel mold of a different shape. A pair of wrestling shoes equipped with the Kingetics orthotic was tested during several marathons. The wrestling shoes were then provided to Crary Shoes and to i-generator for evaluation. The boot prototype had wear patterns consistent with the wrestling shoes, to include posterior lateral heel contact wear, wear at the spring pivot location, and spring wear at the distal (toe) end. Also discussed was the possibility of adding a small section of composite material under the spring pivot attached to the boot prototype to reduce wear by increasing the load over a greater surface area.

After receiving the Kingetics prototype orthotic and the prototype boot housing, i-generator was able to translate the physical dimensions of each part into measured drawings suitable for consistent, repeatable construction. i-generator also used these dimensions along with the physical prototypes to design and develop a prototype military boot where the prototype orthotic, consisting of the spring plate and a foot cradle, was to be an integral part of the boot's sole. The design utilized stitch-down construction and an extra large throat portion of the upper that allowed for the feasible installation of the insole unit. Materials and construction techniques were selected that would allow the boot to be produced at a mass scale. i-generator provided measured cross-section views of the prototype orthotic, detailed upper renderings showing how the orthotic fit with the upper and outsole of the boot, and illustrations that explained the construction of the boot and its assembly with the orthotic.

Mechanical advantage has been addressed in this task. The governing mechanistic principles and basic design of the Kingetics orthotic are illustrated in Figures 1 and 2. As the foot approaches the ground at angle ϴ, the spring orthotic absorbs the impact force of the ground F by bending (Figure 1). The tension in the bent spring is stored as potential energy. As the heel is raised, the orthotic pushes against the ground reactive force G and the moment M helps to restore the foot to a horizontal position. As with a cantilever beam, the force exerted on the proximal end of the spring plate can be expressed as:



$$F = (h^3 w E d)/4L^3 \qquad (1)$$

Where w and h are respectively the width and height of the spring plate, L is the length of the spring plate from the dorsal heel pivot to the proximal end, d is the deflection and E is the tensile modulus.

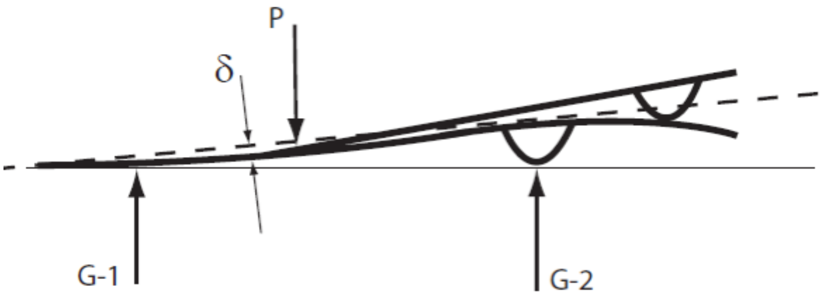
As the spring unloads, and the distal end contacts the ground in readiness for the push-off phase of the gait cycle, loading at point P (Figure 2) combines with normal reactive forces at G-1 and G-2, causing additional bending in the spring around the ball of the foot. The potential force stored in the spring plate at this phase of the cycle is given by:

the Kingetics
ycle

$$F = (h^3 4 w E d)/L^3 \qquad (2)$$

It is evident that by manipulating the dimensions of the spring plate, the relative location of the pivots, and the material properties of the plate, the performance of the spring can be varied over a wide range. For example, a small decrease in the distance between pivots results in large increase in the normal force exerted on the heel.

Kingetics LLC has produced an orthotic device that has shown much promise in preliminary testing. It is noted that other than the two designs selected for Phase I testing, no other systematic design variations have been made.



Based on the principles and formulations described above, we have created an orthotic design that has the capability of efficiently reducing load rates while increasing energy storage and return. We have also have investigated the properties of tensile strength, density, modulus of elasticity, and the ratio of stiffness to density. All of these properties relate to our discussion of the mechanical advantage and the mechanical principles. In addition, we have compared properties of the Kingetics orthotic material to the properties of some standard materials. The table and related chart may be found at Appendix C.

Conclusion: The tensile strength (the value E, in the above equations) of the Kingetics orthotic (760 MPa) is quite high, thus providing excellent performance and mechanical advantage. Additionally, the ultimate tensile strength versus density ratio (571) is quite high, indicating high performance levels and mechanical advantage, combined with a favorable weight advantage.

Task 4; Evaluate the Orthotics in Relation to Various Performance Criteria:

SubTask 4.1; Apply the ASTM F2412-05 puncture test and demonstrate that the orthotics outperform the related puncture standard:

The puncture resistance testing was completed at the CAPE Lab. *The Kingetics Orthotic Spring Plate puncture resistance, 1815 Newtons, averaged approximately three times more than the military boot sole assemblies, at 665 Newtons. The Sport Model Heel Cradle puncture resistance, at 3065 Newtons, averaged approximately five times more than the military boot sole assemblies. The Safety Model Heel Cradle puncture resistance, at 6897 Newtons, averaged approximately ten times more than the military boot sole assemblies.*

Additionally, in a related standard, ASTM 2413-05, the puncture resistance for protective footwear has been established as 270 pounds of force, or 1202 Newtons. Each of the individual components in the Kingetics orthotics exceeds this related standard.

The reports of the puncture resistance testing may be found at Appendix D.

SubTasks 4.2, 4.3, and 4.4 (General):

The literature review by Biomechanigg Research, Inc. (BRI) covers the period 1947 to 2011. It is considered to be exhaustive. The review was evaluated for content and applicability, and an initial evaluation of the orthotics is provided in this report, with reference to the various performance criteria. The published citations discussed in the literature review may be found in the References Section, and BRI's analysis of their literature search may be found in Appendix B.

The literature review and its analyses were used in the SubTasks 4.2, 4.3, and 4.4 to address the specific testing criteria for the prototype orthotics.

Subtask 4.2: Demonstrate that the orthotics can reduce injury risk by >10%:

Repetitive Strain Injuries: Researchers have reported reduced injury frequencies of 10-13% with regards to overuse injuries of the foot, 10-20% for plantar fasciitis, 5% for metatarsal stress fractures and 4% for tibial stress syndrome due to insert/orthotic use.

Pain: Inserts/orthotics have shown to provide substantial pain relief at the Achilles tendon, calf and lower back.

Acute Injuries: No clear link was identified between footwear construction and acute risk of injury.

Conclusion: ***BRI predicts that repetitive strain injuries and pain could be reduced by 8%-12%,*** because it is speculated that the design of the Kingetics LLC system could reduce the levers that often characterize military boots, which are often correlated to high loading. High loading has been associated to an increase in repetitive strain injury risk and pain. BRI predicts no significant effect on acute injuries.

Subtask 4.3: Demonstrate a significant decrease in oxygen consumption:

Weight Effect: There is general agreement in the literature that each 100g reduction in shoe mass results in a 0.7 to 1.0% reduction in metabolic cost during locomotion.

Stiffness Effect: Reductions in energy expenditure of approximately 1% were observed when individuals used stiffer soles and when they used the most comfortable insoles while running.

Energy Return Effect: The effectiveness of insoles/orthotics in returning energy depends on the timing, frequency and location of the returned energy. Internal investigations at BRI have shown energy returns of up to 7%.

Conclusion: ***BRI predicts that the orthotic will significantly reduce energy expenditure during walking by over 1%.*** This is based on the following speculations: 1) A reduction in shoe weight by over 100 grams is feasible, and 2) The system has both a forefoot and rearfoot factor which may affect energy positively. It is speculated that the timing of the energy return can be addressed with this device. Lastly, BRI predicts that the insert's stiffness will not play a role in reducing energy costs as this is more applicable for sprinting and jumping movements.

Subtask 4.4: Increase subjective comfort ratings by 10% when compared to traditional combat boot:

Pressure: The most comfortable footwear conditions were found to involve a more even distribution of pressure across the plantar surface of the foot. The shape of the current orthotic design provides midfoot support, where usually low values in pressure are found.

Injury Risk and Energy: Reducing both the risk of injury and/or the loss of energy has been associated with higher comfort ratings.

Multiple Models: The perception of comfort is largely dependent on subject specific characteristics indicating that a range of footwear solutions may be required for the purpose of achieving optimal comfort.

Conclusion: ***BRI predicts a 10% or greater subjective comfort rating when compared to traditional military boots*** because of a more even pressure distribution, a reduction in the risk of injury, a reduction in the loss of energy, and the offering of multiple designs (3 or more).

While no Human Subject Testing has occurred during this Phase I effort, we have anecdotal reports of the orthotics being used by partners in and associates of Kingetics LLC for several years and over a wide range of conditions, from walking on concrete factory floors to running marathons over broken and rugged terrain. The informal reports indicated that the orthotics performed well and provided the mechanical advantages as predicted in our proposal, as well as providing (subjective) comfort to the user.

Subtask 4.5: Fire retardant tests:

The flammability testing of the Kingetics orthotics has been completed for both the horizontal and the vertical burning tests. According to UL 94, a rating of "HB" for the horizontal burning tests, and a rating of "V-0" for the vertical testing are the best ratings possible for the device tested. The Final Test Report is provided at Appendix E.

Conclusion: The horizontal burn tests resulted in a rating of "HB" for the Spring Plate and for both the Safety and Sport Heel Cradles. The vertical burn tests resulted in a rating of "V-0" for the Spring Plate and for both the Safety and Sport Heel Cradles.

Task 5: Assess Useful Life Expectancy of the Orthotic and Estimate Manufacturing Costs:

A. Useful Life Expectancy Analysis:

1) **Composite materials – General:** Composite materials are known to perform tens of millions of cycles without showing any signs of fatigue if used within the designed parameters. One of the advantages of composite materials usage in the latest aerospace structures is the fact that inspections of crack propagations are performed less often, thus keeping the structure in service longer and saving on costly inspections and repairs. Composites also show very limited performance variations due to changes in climate. Fatigue testing of composite materials can be conducted using a variety of procedures, and feedback from this testing should be incorporated into future designs. Cyclic fatigue testing of the Kingetic orthotic is currently scheduled for the Phase I Option, if funded.

2) **Kingetics Orthotics – General:** At our manufacturing facility, the technicians have used the Sport Model devices in a working environment for over 1000 hours over an 8 month period. This has included using the device in a variety of daily tasks including walking, running, stair and ladder climbing, carrying heavy objects, squatting and kneeling and jumping in a variety of climatic conditions. The devices have shown only minor scuffing wear, and no structural degradation.

3) **Kingetics Orthotics Heel Cradle:** For rugged field and office (all surface) use, it is estimated that the cradles will have a long life cycle (greater than two years), since it is a rigid, non-flexing component made of hardened carbon fiber. Some frictional wear has occurred at the junction points (Heel Cradle pivot to Spring Plate and Heel Cradle forefoot to Spring Plate), but this wear has not affected the function of the orthotic device.

4) **Kingetics Orthotics Spring Plate:** When walking on flat surfaces (such as manufacturing plant and office work), the Spring Plates may experience a life expectancy of greater than one year. For continuous activities with high impact loads such as running on flat surfaces or in rugged terrain, the Spring Plates may experience a life expectancy of a year. Note that this estimate is based on the anecdotal usage of the prototype orthotic, and may be better estimated once the Human Subject Testing is conducted during Phase II, if funded. As a composite material, the Spring Plate should function well unless it is subjected to an extremely adverse situation. The Kevlar layers, however, will still keep the orthotic intact and will still offer ballistic protection.

5) **Kingetics Orthotics Boot Housing:** The boot housings have held up well when walking on carpeted and finished flooring. The sole material does show increased wear

on asphalt and highly abrasive surfaces due to the increased friction and traction force created by the rearfoot contact and forefoot toe-off spring action and plantar to the spring pivot. The boot uppers are expected to have a life expectancy consistent with existing military footwear because the construction of both the prototype and issue-type military footwear (*e.g.* the Belleville DES 390) is similar.

B. Manufacturing Cost Estimate:

The design of the Kingetics orthotic device has incorporated ease and consistency of manufacturing to the greatest extent possible for this prototype. The prototype designs were manufactured in a composite R&D facility using relatively low cost equipment which is readily available. No specially constructed equipment was required.

Although the materials are not subject to a significant decrease in cost at higher volumes, the time investment (labor costs) can be greatly reduced as production capacity increases. This will require substantial investment in equipment and these costs will have to be amortized over equally large production runs of the device. The estimates provided as part of this analysis, are, necessarily, based on the cost of production for the prototype only.

The current processing costs are nearly 4 times the material cost that can be expected in low production volumes. It would be very likely that an appropriate investment in processing machinery could achieve a ratio of 1 to 1.

Further research, development, and analysis of processing capabilities and product demand would be required to determine the most cost effective course of action, and these issues will be addressed in the follow-on Phases, if funded.

Task 3, which has been completed and is discussed elsewhere in this report, involved the development of a synergistic boot housing design with one of our subcontractors, i-generator. In a parallel and separately-funded effort to this SBIR contract, Kingetics entered into a working relationship with Crary Shoes to create a boot prototype that modeled the designs provided to Kingetics by i-generator. Please refer to Appendices A-1 and A-2 for the design diagrams and for the pictures of the actual boot prototype that was produced.

Key Research Accomplishments

1. **Task 1:** After reviewing multiple concepts, two specific design concepts of the Kingetics orthotic, the Sport and the Safety Models, were selected for Phase I testing and evaluation. It is noted that the orthotic design concept sample sizes will have to be expanded to include the standard footwear sizes for both males and females.

2. **Task 2:** The two selected designs of the Kingetics orthotic, the Sport and the Safety Models, were created using Kevlar and carbon fiber composite materials. After testing an alternative ballistic material, Spectra®, it was determined that the composites used in the orthotics were the best available materials.

3. **Task 3:** The tensile strength, at 760 MPa, of the Kingetics orthotic is quite high, thus providing excellent performance and mechanical advantage. Additionally, the ultimate tensile strength versus density ratio of 571 is quite high, indicating high performance levels and mechanical advantage, combined with a favorable weight advantage.

4. **Task 4:** A literature research was conducted by one of our subcontractors, BRI, which resulted in an exhaustive literature review and analysis that covers the period from 1947 to 2011. The review and analysis enabled BRI to make some fundamental predictions in the Phase I task assignments, but, more importantly, has provided BRI with information and data that will be essential during the Phase I Option and Phase II research efforts, if funded.

5. **SubTask 4.1:** All of the components of the Kingetics orthotics individually exceed the ASTM 2413 requirement of 1202 Newtons for puncture resistant footwear. Puncture Resistance Testing was conducted at the CAPE Lab, a facility that is part of the South Dakota School of Mines and Technology. The testing was IAW ATSM 2412-05. The results of the testing provided consistent, reproducible results, and all components of the Kingetics orthotic exceeded the ASTM 2413-05 standard of 1202 Newtons: Spring Plate: 1815 Newtons; Sport Heel Cradle: 3087 Newtons; and the Safety Heel Cradle: 6087 Newtons. For comparison purposes, the sole assemblies from issue-type military footwear (Belleville DES 390) was tested and found to have a puncture resistance of 665 Newtons.

6. **Subtask 4.2:** BRI predicts that repetitive strain injuries and pain could be reduced by 8%-12%, because it is speculated that the design of the Kingetics LLC system could

reduce the levers that often characterize military boots, which are often correlated to high loading. High loading has been associated to an increase in repetitive strain injury risk and pain. BRI predicts no significant effect on acute injuries.

7. **SubTask 4.3:** BRI predicts that the orthotic will significantly reduce energy expenditure during walking by over 1%. This is based on the following speculations: 1) A reduction in shoe weight by over 100 grams is feasible, and 2) The system has both a forefoot and rearfoot factor which may affect energy positively. It is speculated that the timing of the energy return can be addressed with this device. Lastly, BRI predicts that the insert's stiffness will not play a role in reducing energy costs as this is more applicable for sprinting and jumping movements.

8. **SubTask 4.4:** BRI predicts a 10% or greater subjective comfort rating when compared to traditional military boots because of a more even pressure distribution, a reduction in the risk of injury, a reduction in the loss of energy, and the offering of multiple designs (3 or more).

9. **SubTask 4.5:** The horizontal burn tests resulted in a rating of "HB" for the Spring Plate and for both the Safety and Sport Heel Cradles. The vertical burn tests resulted in a rating of "V-0" for the Spring Plate and for both the Safety and Sport Heel Cradles. Note: According to UL 94, a rating of "HB" for the horizontal burning tests and a rating of "V-0" for the vertical testing are the best ratings possible for the device being tested. Flammability Testing was also conducted at the CAPE Lab, IAW UL 94. The orthotics were tested and were assigned an "HB" rating and a "V-0" rating for the horizontal and the vertical testing, respectively. The ratings are the best ratings allowed by UL 94.

10. **Task 5:** 1) Based upon DEVELOPMENTAL information, manufacturing costs include both labor and material, of which labor is the highest cost percentage. Labor costs can be reduced in mass production by using automation for repetitive tasks and alternative, mechanized production methods. 2) The life expectancy of the Spring Plate may be approximately one year, depended upon usage; while the life expectancies of the Heel Cradles in both the Sport and Safety models may be expressed in years, and probably will last the lifetime of the military footwear.

Reportable Outcomes

Task 1; Create Multiple Concept Designs:

Multiple concepts were considered for the Kingetics orthotic, and two specific designs were chosen for testing and evaluation.

Task 2; Select two promising design concepts and produce prototypes:

The two designs selected, the Sport and the Safety models, were produced in sufficient quantity for the testing and evaluation efforts in Phase I. Critical production and manufacturing data was generated and held for analysis. The manufacturing process was consistent, repeatable, and well controlled, as demonstrated by the uniformity in the finished orthotics.

Task 3: Design Synergistic Boot Housings that Add Mechanical Advantage and Reduce Weight:

Pictures of the boot prototype are at Appendix B. The drawings are at Appendix C. The following comparisons were made against the standard, Belleville 390 DES military boot:

a) Mechanical advantage was shown to be quite positive in terms of a very high Tensile Modulus (760 MPa), a Density (1.33 g/cm), and by calculating a very high Tensile Strength to Density ratio of 571.
b) The boot prototype with the Sport Model orthotic reduced weight by 10%.

Subtask 4.1; Apply the ASTM F2412-05 puncture test and demonstrate that the orthotics outperformed the related puncture standard:

The puncture resistance testing was completed at the CAPE Lab. The Kingetics Orthotic Spring Plate puncture resistance, at 1815 Newtons, averaged approximately three times more than the military boot sole assemblies (665 Newtons). The Sport Model Heel Cradle puncture resistance, at 3065 Newtons, averaged approximately five times more than the military boot sole assemblies. The Safety Model Heel Cradle puncture resistance, at 6897 Newtons, averaged approximately ten times more than the military boot (Belleville 390 DES) sole assemblies.

Two of the Spectra® samples were similar to the Spring Plate composite material and tested at a rough average of 900 Newtons, while the third sample approximated the thickness of the Safety Heel Cradle and tested at 3730 Newtons. The Spectra® material puncture resistance test report is contained in the second report found at Appendix D.

In a related standard, ASTM 2413-05, the puncture resistance for protective footwear has been established as 270 pounds of force, or 1202 Newtons. Each of the individual components in the Kingetics orthotics exceeds this related standard.

SubTask 4.2; Reduction of Risk for Injury:

An exhaustive literature search was conducted by BRI. BRI then made comparisons between the literature search results and the Kingetics orthotics, and predicted that the Kingetics orthotics could reduce the risk of repetitive strain injuries and pain by 8% to 12 %.

SubTask 4.3; Reduction in Oxygen consumption:

Referring to the discussion in Task 3, above, the orthotic and prototype boot housing has a weight advantage over current military footwear. The results from the literature search, combined with the mechanical advantage generated by the orthotic, allowed BRI to predict that the orthotic will significantly reduce energy expenditure during walking by over 1%. This will assist the Warfighter in reducing the consumption of oxygen.

SubTask 4.4; Comfort rating:

By analyzing the reports found during the literature and comparing the attributes of the Kingetics orthotics to the findings in the reports, BRI predicts a 10% or greater subjective comfort rating, when the orthotic is compared to traditional military boots.

SubTask 4.5; Fire retardant tests:

The flammability testing of the Kingetics orthotics included both the horizontal and the vertical burning tests. The horizontal burning tests resulted in a rating of "HB" for the Spring Plate and for both the Safety and Sport Heel Cradles. The vertical burning tests resulted in a rating of "V-0" for the Spring Plate and for both the Safety and Sport Heel Cradles. According to UL 94, a rating of "HB" for the horizontal burning tests, and a rating of "V-0" for the vertical testing are the best ratings possible for the device being tested.

Task 5; Life expectancy estimates and Manufacturing cost estimates:

Life expectancy estimates vary according to the type of use for the orthotic. The Spring Plate is the most affected by the type of use, and its life expectancy should exceed one year. The Heel Cradles for both the Sport and the Safety Models should last in excess of a year, and probably throughout the lifetime of the military footwear.

Manufacturing costs were estimated based on DEVELOPMENTAL, or One-off, production costs. The cost of materials is expected to remain stable, while production costs should decrease dramatically, once mass production techniques have been adopted.

Task 6; Produce a Final Summary Report:

This report constitutes fulfillment of the assigned task.

Conclusions

The primary goal of the SBIR Phase I project was to demonstrate the feasibility of the Kingetics' orthotic that will reduce injury and enhance ambulatory performance using advanced composites. The overall goal for this multi-phase SBIR project was to develop, prototype, validate, field-test, and deploy the envisioned next-generation boot for use by the Army, other DOD components, and key markets in the government and civilian sectors.

Two designs, the Sport and the Safety models, were evaluated and selected for initial testing. Evaluation of an alternate composite material (Spectra®) confirmed that the current composites were the best possible choices. The Spectra® material performed well enough, however, to be retained as a material of interest in further Phase II studies, if funded, that are designed to reduce the overall weight of the orthotic.

Boot housings and the associated conceptual drawings were created for evaluation. The general appearance of the boot housing is that of the standard issue, desert combat boot. The boot prototype mechanically assisted the function of the Kingetics orthotic when utilized on rugged, mountainous trails as well as on flat, concrete surfaces. Improvements in the boot housing and the orthotic will be addressed if this project is selected for additional funding in Phase II.

The puncture resistance of the Kingetics Orthotic Spring Plate averaged three times higher; the Sport Model Heel Cradle averaged five times higher; and the Safety Model Heel Cradle averaged ten times higher, all compared with the Belleville DES 390 military boots. The components of the orthotic each, individually, exceeded the puncture resistance standard set in ASTM 2413-05.

Several of characteristics of the orthotic and the boot housing require Human Subject Testing (HST) to fully evaluate those characteristics. Extensive HST is planned for Phase II, if funded, and important preparations will be made during the Phase I Option, if activated.

Because HST was not performed in any of the Phase I tasks, one of our subcontractors performed an exhaustive literature review and used the results of the study to address several of the key characteristics: *Repetitive Strain Injuries*: Researchers have reported reduced injury frequencies of 10-13% for overuse injuries of the foot, 10-20% for plantar fasciitis, 5% for metatarsal stress fractures and 4% for tibial stress syndrome due to insert/orthotic use. *Pain*: Inserts/orthotics have shown to provide substantial pain relief at the Achilles tendon, calf and lower back. The conclusion was that ***Repetitive strain injuries and pain could be reduced by 8%-12%.*** The Kingetics orthotic could reduce the levers that often characterize military boots, which are often correlated to forces from high impact with the ground. Such high impact forces have been associated to an increase in repetitive strain injury risk and pain.

Weight reduction: The literature suggests that each 100g reduction in shoe mass results in a 0.7 to 1.0% reduction in metabolic cost during locomotion. *Stiffness Effect*: Reductions in energy expenditure of approximately 1% were observed when individuals used stiffer soles and the most comfortable insoles. *Energy Return Effect*: The effectiveness of insoles/orthotics in returning energy depends on the timing, frequency and location of the returned energy, with demonstrated energy returns of up to 7%. The conclusion was that ***the orthotic will significantly reduce energy expenditure during walking by over 1%***; because: 1) A reduction in shoe weight by over 100 grams is feasible, and 2) The system has both a forefoot and rearfoot factor which may affect energy positively.

Increasing subjective comfort ratings by 10% was difficult to assess without HST, but anecdotal reports were compiled for of the orthotics used over a wide range of conditions, from walking on concrete factory floors to running marathons over broken terrain. The informal reports indicated that the orthotics perform well and provide the mechanical advantages as predicted, as well as providing (subjective) comfort to the user. Specific characteristics involved with comfort were evaluated and include: *Pressure*: The most comfortable footwear conditions involve a more even distribution of pressure across the plantar surface of the foot. The shape of the current orthotic design provides midfoot support, with low pressure values. *Injury Risk and Energy*: Reducing both the risk of injury and/or the loss of energy has been associated with higher comfort ratings. *Multiple Models*: A range of footwear solutions may be required to achieve optimal comfort. The conclusion was that a ***10% or greater subjective comfort rating will result when compared to traditional military boots*** because of a more even pressure distribution, a reduction in the risk of injury and in the loss of energy, and the offering of multiple designs.

Flammability tests were conducted IAW UL 94 and resulted in an “HB” rating for horizontal burning tests, and a “V-0” rating for vertical burning tests. These are the best UL 94 ratings possible. If the materials of the orthotics are substantially changed after Phase II evaluations, the puncture resistance and flammability testing will be repeated as appropriate.

The Sport and the Safety models were manufactured for testing and evaluation. The production processes and procedures for both models are fully documented. That documented information will be used to develop and evaluate the manufacturing and distribution process that will be necessary in Phase II, if funded. Anecdotal usage reports established life expectancy for the prototype orthotics at approximately one year or more. Estimated manufacturing costs were based on developmental costs for the prototype orthotics. During Phase II efforts, if funded, costs of manufacturing and production, as well as assessing the most appropriate method of manufacturing will be studied. It is envisioned that a pilot manufacturing plant will be established to further document the issues surrounding the manufacturing and production process.

As a result of the research conducted in Phase I, the overall evaluation indicates that the Kingetics orthotic has successfully met or exceeded the expectations as an improvement to military footwear. Further improvements and modifications are possible and will result from the additional evaluations conducted during Phase II, if funded.

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Appendices:

Detailed List **Page**

Appendix A-1: Conceptual Drawings

Figure A-1-1: Lateral View, Prototype Drawing

Figure A-1-2: Lateral View, with Kingetics orthotic in place

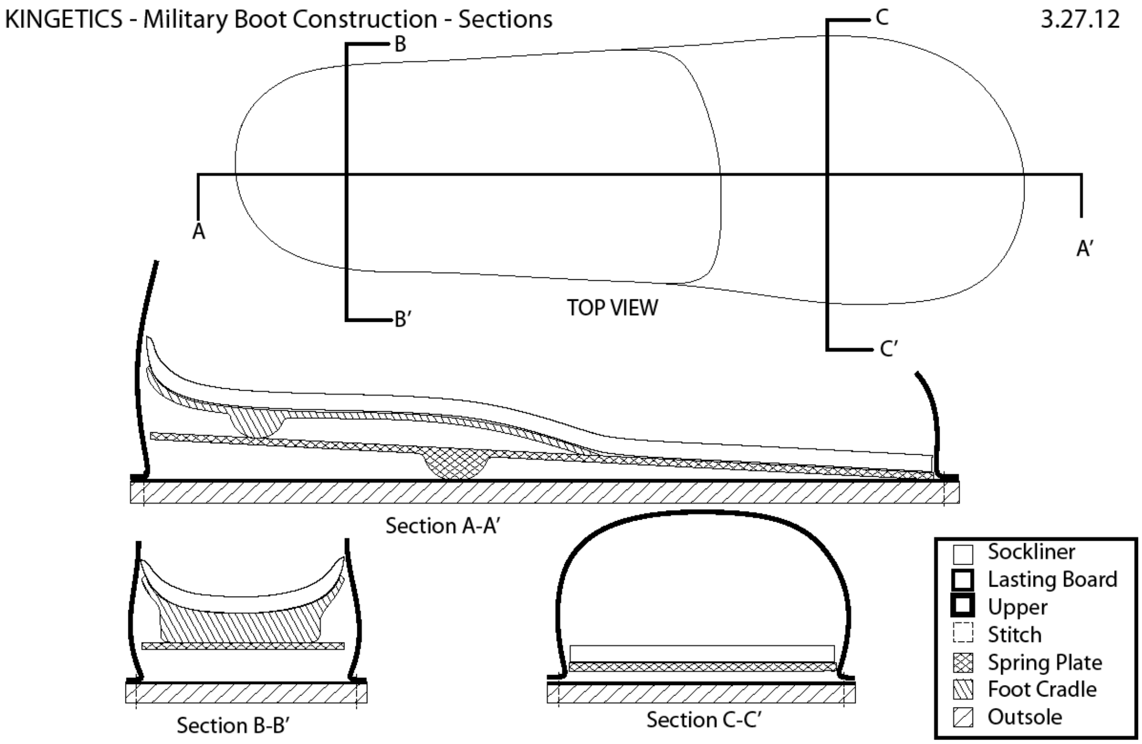

Figure A-1-3: Line Drawing, Prototype and Sole

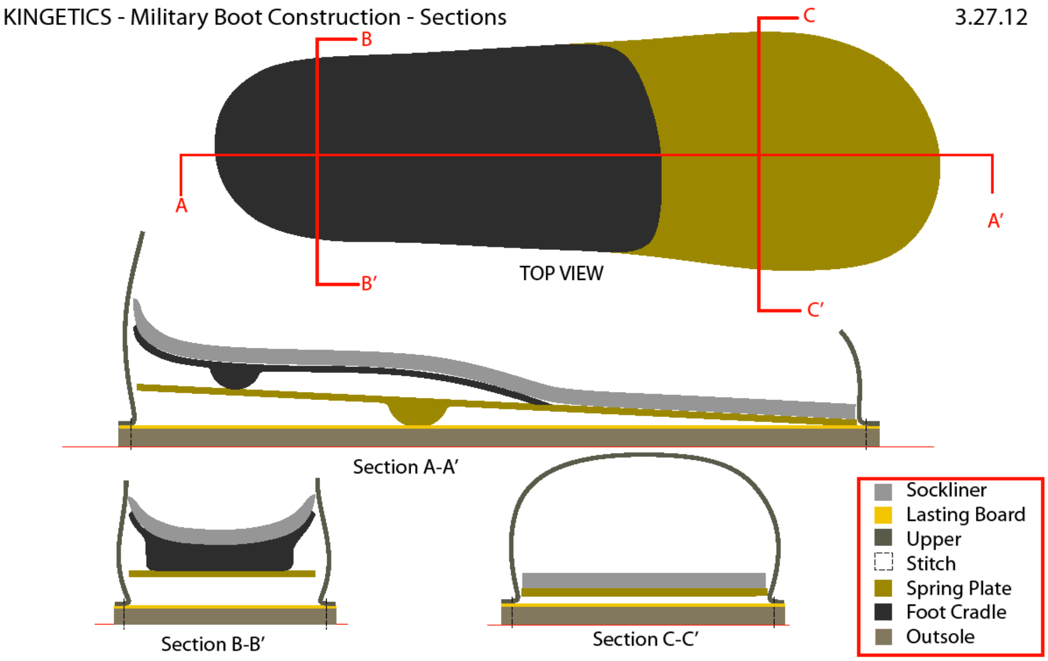

Figure A-1-4: Detailed Drawing of Prototype and Sole

Appendix A-2: Prototype Pictures

Figure A-2-1: Side View, Crary Prototype

Figure A-2-2: Rear View, Crary Prototype

Figure A-2-3: View of the sole, Crary Prototype

Figure A-2-4: The boot prototype, during field testing

Appendix B: BRI Literature Review

Kingetics, LLC **April, 2012**

Biomechanical effects of shoe inserts/ orthotics on injury, energy and comfort

A Literature Review

Human Performance Laboratory

Biomechanigg Research Inc.

BRI

A literature review for Kingetics, LLC summarizing the current knowledge on the effects of shoe insert/orthotic use with respect to the potential for the Kingetics, LLC insole system to decrease injury frequency, optimize energy demands of locomotion and increase comfort.

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Executive Summary

Purpose

Kingetics, LLC are developing a novel military boot insole system with the goal of reducing injury frequencies, optimizing energy demands of locomotion and increasing subjective comfort. The objective of this literature review was to:

> **Summarize the current knowledge regarding the effects of shoe inserts/ orthotics on (a) the frequency of overuse and acute injury as well as pain, (b) the metabolic and mechanical energy demands of locomotion and (c) the perception of comfort.**

Method

A literature review was conducted with the specific focus on the effects of footwear modifications, inserts and orthotics on the frequency of overuse and acute injury as well as pain relief, the metabolic cost of locomotion, the mechanical energy requirements of locomotion and the perceived comfort of footwear conditions. 106 journal papers and books, covering aspects of health, military and sports research, have been included in this review, covering the years 1946 – 2011. These articles have been summarized and the findings were interpreted with reference to the stated aims of the Kingetics, LLC insole system. Conclusions from the respective sections have been highlighted to clearly indicate the likely magnitude of the effects of footwear interventions. Based on this literature review and also on a visual assessment of the Kingetics, LLC insole system, a functional explanation of the predicted effects of wearing this insole system is provided.

Results

Injury

The Kingetics, LLC insole system aims to “reduce injury risk by >10%”. From the literature, effects of insoles/orthotics were separated into categories that included repetitive strain injuries, acute injuries and pain relief. Some evidence supports the use of selected orthotics for reducing the frequency of a number of overuse injuries and for providing pain relief. However, due to a small number of studies, a lack of consistency between these studies and a general lack of evidence regarding long term benefits from insole/orthotic use, at this point in time, these conclusions must be considered relatively weak. Nonetheless, researchers have reported reduced injury frequencies of 10-13% with regards to overuse injuries of the foot, 10-20% for plantar fasciitis, 5% for metatarsal stress fractures and 4% for tibial stress syndrome due to insert/orthotic use. Furthermore, inserts/orthotics were shown to provide substantial pain relief at the Achilles tendon, calf and lower back.

Albeit weak, evidence supports the use of insert/orthotic devices to reduce overuse injury frequencies by 4-20%.
Pain relief may be substantial for specific anatomical sites, particularly at the feet. The long-term effect of these benefits is currently unknown.

No clear link was identified between footwear construction and acute risk of injury. Heel cushioning systems have resulted in contradictory outcomes. However, evidence suggests that shoe construction has little direct impact on acute injury occurrence. The effects of inserts/orthotics on skeletal "alignment" are typically small and inconsistent. The effects of most mechanical adjustments are subject specific and therefore, the effects of interventions cannot currently be predicted.

Energy

The Kingetics, LLC system aims to "significantly reduce oxygen consumption" by reducing shoe mass and increasing energy return from the orthotic. There is general agreement in the literature that each 100g reduction in shoe mass results in a 0.7 to 1.0% reduction in metabolic cost during locomotion.

Heel cushioning and energy storage and return devices have also led to reductions in the metabolic cost of locomotion. Energy savings were in the range of 1.6-3.7%. The effectiveness of such devices is dependent on the movement task (e.g. walking or running) and little evidence exists for commercial systems that successfully reduce the metabolic cost of locomotion.
Insole/orthotic stiffness and comfort may also affect energy expenditure. Reductions in energy expenditure of approximately 1% were observed when individuals used stiffer soles and when they used the most comfortable insoles while running.

Research demonstrates that insole stiffness may affect performance. Sprinting times were reduced and jumping height was increased when individuals used stiffer insoles. These performance increases were achieved by reducing energy loss at the midfoot. However, results were subject specific and may be related to muscle strength and perceived comfort.
Storage and return of energy using an insole/orthotic device is generally difficult to achieve and, using current EVA and PU materials, typically results in small energy gains (< 1%). The effectiveness of insoles/orthotics in returning energy depends on the timing, frequency and location of the returned energy. Energy returns of 7% have been observed.

Reducing footwear mass reduces the metabolic cost of locomotion by 0.7-1.0% per 100g reduction.

> **Using current insole material technologies, minimal energy return is feasible. Alternative materials and orthotic/insole construction may lead to substantially greater and functionally relevant energy return. However, this has not yet been demonstrated in a product.**

Comfort

Researchers have related footwear comfort to plantar pressure distribution. Accordingly, the most comfortable footwear conditions were found to involve a more even distribution of pressure across the plantar surface of the foot. Comfort may also be affected by rearfoot movement, foot and leg alignment and foot sensitivity. The perception of comfort is largely dependent on subject specific characteristics indicating that a range of footwear solutions may be required for the purpose of achieving optimal comfort.

Predicted effects of Kingetics, LLC system

Injuries could be reduced because it is speculated that the design of the Kingetics LLC system could reduce the levers that often characterize military boots, which are often correlated to high loading. With respect to energy return, the system has both a forefoot and rearfoot factor which may affect energy positively. Lastly, if the shoes are constructed to reduce pain, and injury risk, while increasing energy return or reducing the loss of energy, then increased comfort is a likely outcome.

> **There is a potential for the Kingetics LLC system to reduce injuries, return energy and improve comfort when compared to standard military boots.**

Introduction

Military service personnel are involved in highly demanding physical activities during training and in the battlefield and are particularly prone to pathologies of the lower limbs (Jacobs and Berson 1986; Ross 1993). Strategies to assist in task performance and reduce the risk of injury include footwear interventions using inserts and orthotics. Shoe inserts and orthotics are advocated for use for a wide range of purposes including aligning the skeleton, improving damping of impact forces, providing guidance and control for foot and leg movement, improving sensory feedback and comfort, and reducing injury frequencies. The current area of application for inserts and orthotics is broad, ranging from athletes who aim to prevent injuries and/or improve performance (Hume et al., 2008), to clinical interventions designed to assist patients with diabetes (Kato et al., 1996; Müller et al., 1997; Kästenbauer et al., 2004), correct flat-footedness (Leung et al., 1998), compensate for osteoarthritic knees (Ogata et al., 1997) and treat or prevent rheumatoid foot disease (Grifka, 1997; Shrader and Siegel, 1997).

Military boots serve the purpose of protecting the feet of the soldier from the external environment. The boot, therefore, must meet a number of criteria concerning material properties that provide blast and fire protection. As a result, military boots are constructed with an emphasis on protection rather than performance. Studies have shown that the use of comfortable insoles in a military boot can have a positive impact on the health of the soldier. However, these interventions do not address the design of the military boot itself. The insole system proposed by Kingetics, LLC provides a new approach to the construction of a boot sole. A combination of distinct mechanical and material design features are used with the aim of:

1. **Reducing injury risk by >10%**
2. **Significantly reducing oxygen consumption (= energy demand)**
3. **Increasing energy storage and return**
4. **Increasing comfort by 10% compared to traditional combat boots**

The objective of this literature review is to summarize the likely effects of Kingetics, LLC orthotics on locomotion and their potential for preventing injury, enhancing performance and increasing subjective comfort. This review will determine the likely magnitude of such effects on specified variables based on observations on the use of orthotics and inserts in health, military and sports settings. The likelihood of the orthotic being successful in attaining the desired results will be assessed based on the reviewed literature in conjunction with a visual evaluation of the prototype by Dr. Benno Nigg. All sections, which have both the support from the literature as well as from Dr. Nigg, will be elaborated upon with a functional explanation designed to predict and define the beneficial outcomes from wearing the orthotic.

Injury

This section is concerned with the current evidence relating to the concept of acute and repetitive strain injury prevention through the use of orthotics and inserts. The aim of the Kingetics, LLC orthotics system is to "reduce injury risk by >10%". Variables of particular interest are tibial rotation, pronation, arch support and hip abduction. Furthermore, the system aims to decrease the risk of musculoskeletal overuse injuries by mitigating impact and increasing stabilization. The following sections will address the specified aims by reviewing the current evidence for the use of inserts and orthotics to prevent repetitive strain and acute injuries as well as for reducing pain.

Repetitive Strain Injury

Inserts and orthotics are used to relieve repetitive strain injuries that frequently affect populations involved in highly demanding physical activities. Injuries thought to be affected by inserts and orthotics include plantar fasciitis, posterior tibial syndrome, Achilles tendinitis, patellar femoral pain syndrome or osteoarthritis (Gross et al., 1991; Maclellan and Vyvyan, 1981). Gross et al. (1991) performed a survey of long distance runners showing a multitude of orthotic shoe insert uses: to counter excessive foot eversion (31.1%), plantar fasciitis (20.7%), Achilles tendinitis (18.5%), leg length discrepancy (13.5%), patello-femoral disorders (12.6%), and shin splints (7.2%). Of the 347 respondents, 76% reported complete recovery or substantial improvement in symptoms due to the use of orthotics. Prospective studies showed that shock-absorbing or visco-elastic shoe inserts reduced the frequency of overuse injuries of the foot and reduced tibial stress syndrome in military populations (Finestone et al., 1992; Milgrom et al., 1992; Schwellnus et al., 1990). Milgrom et al. (1992) followed 390 recruits during 14 weeks of training. The findings indicated that recruits training in a modified basketball shoe had a significantly lower incidence of metatarsal stress fractures (3.5%) and foot overuse injuries (13.6%), compared with standard infantry boots, but the overall incidence of overuse injuries was not reduced. Schwellnus et al. (1990) compared the effects of a shock absorbing neoprene insole (237 recruits) to standard military footwear (1151 recruits) during a 9 week basic training program. Their findings showed that neoprene insoles significantly reduced the overall incidence of overuse injuries (~10%) and specifically the incidence of tibial stress syndrome (4%). In contrast, Gardner et al. (1988), investigating the effects of a visco-elastic polymer insole added to a standard military boot, observed no significant reduction in injury incidence (stress fracture, plantar fasciitis, ankle sprains, knee strains or Achilles tendinitis) for 3,025 US Marine recruits during a 12 week training program.

It has been suggested that shoe inserts and orthotics reduce the symptoms of injuries by realigning the foot or by a cushioning effect of the insert material (Gross et al., 1991). For instance, an alignment strategy may be pursued to reduce foot eversion or pronation. A study performed by Nigg et al. (1998) used five identically shaped inserts of different material composition in an attempt to reduce foot eversion and tibial rotation. 12 subjects performed heel-toe running at 4 m/s where foot eversion and tibial rotation during ground contact were quantified using skin-mounted markers. Only one of the 12 subjects displayed the desired result while other subjects demonstrated a reduction of foot eversion and increase in tibial rotation for all inserts or a reduction in foot eversion but an increase of tibial rotation for only a selection of conditions. These findings indicate that changes were not consistent, typically small (1 to 2 degrees), and subject specific. Moreover, most changes were contrary to what was expected. Possible reasons for these observations include the fact that the tested insoles were not custom made, the use of a non-homogeneous population and that the measured variables addressed the movement of the shoe rather than the skeleton.

Shortcomings of the above study were addressed by Mündermann et al. (2002, 2003 and 2004). 21 recreational runners (9 male and 12 female) were recruited to quantify the effects of (a) custom-molded and non-custom-molded orthotics and (b) posted and not posted orthotics on kinematics, kinetics, resultant joint moments, and muscle activity. All subjects were classified as pronators in two independent assessments by a podiatrist and a biomechanist using 2-D video analysis. Subjects wore running sandals, which allowed marker placement directly on the skin of the calcaneus rather than on the shoe. The molding condition of the orthotics was posted intrinsically to calcaneus neutral. The posting condition was applied extrinsically. Test subjects performed a two-week accommodation period followed by three testing sessions per week for three weeks using one of four orthotic conditions. The results of the study showed that custom-made orthotics did not affect ankle joint eversion. Inserts/orthotics increased muscle activity in most cases. The authors concluded that this may have been due to the leg “fighting” the kinematic changes induced by the inserts/orthotics. Orthotics therefore did not substantially affect kinematics since the muscles compensated for the induced changes. Furthermore, the inserts/orthotics increased resultant knee joint moments in most cases. Changes in ankle and knee moments and centre of pressure (COP) path were seemingly random indicating the existence of individual strategies for coping with the perturbation induced by the orthotics. It was concluded that there were no “accommodation effects” to the orthotic interventions in terms of kinematics, kinetics, and muscle activity.

It has been suggested that high resultant knee joint moments for tibial abduction/adduction and tibial rotation are associated with the development of knee injuries (Scott and Winter, 1990; McClay and Manal, 1999). Furthermore, it has been proposed that “high” resultant knee joint moments are associated with the development of patello-femoral pain syndrome (PFPS) (Stefanyshyn et al., 1999). In this study, the prospective and retrospective results showed significantly and substantially higher resultant knee abduction impulses for a group of subjects with PFPS compared to a control group. Consequently, it is suggested that reducing the resultant knee abduction moments and the corresponding internal forces and stresses using orthotics/inserts may be beneficial (Bates et al., 1979; Novick and Kelley, 1990; McCulloch et al., 1993; Eng and Pierrynowski, 1994; Nawoczenski et al., 1995; Nigg et al., 1998; Crenshaw et al., 2000; Stacoff et al., 2000).

A study (Nigg et al., 2003) was performed to address the questions of the effect of shoe inserts/orthotics on the centre of pressure (COP) of the ground reaction force and their effect on resultant ankle and knee joint moments. 15 male subjects ran at 4.0 ± 0.2 m/s using four different shoe inserts: using 4.5 mm postings either medially or laterally (full lateral, full medial, half lateral, and half medial) and the neutral insert that was delivered with the shoe. Pressure distribution data were collected for the right foot using a pressure insole system and changes in COP path was described. A standard inverse dynamics approach was used to calculate resultant joint moments at the knee joint. The study found that the effects of the chosen insert interventions on individual movement characteristics were small and inconsistent. This result was in agreement with the results of many previous studies (Smith et al., 1986; Nigg et al., 1987; Nigg and Morlock, 1987; Novick and Kelley, 1990; McCulloch et al., 1993; Eng and Pierrynowski, 1994; Nawoczenski et al., 1995; Nigg et al., 1998). Insert interventions for this normal, healthy population did not achieve the goal of aligning the skeleton, with small and inconsistent effects of inserts on lower extremity kinematics. Individual test subjects did not show an anticipated medial shift of the center of pressure path. Subject reactions to the inserts were not systematic and were often opposite to those expected or random. Similar observations were made for changes in ankle and knee joint moments. Changes for the various insert interventions were not consistent. Relative changes were small for foot plantarflexion and knee extension moments, which are primarily responsible for locomotion. In contrast, the effects were substantial for ankle inversion and adduction moments, as well as knee abduction and external rotation moments, which are primarily responsible for dynamic stability of the lower extremities. Only one insert intervention (the full medial insert) produced a reaction that was systematic/ consistent and significant. The authors concluded that the tested insert interventions: did not affect the ankle and knee joint moments responsible for actual locomotion; affected the ankle and knee joint moments more associated with dynamic stability; and could not be used consistently to reduce knee joint moments. An important observation was that different subjects displayed individual and unpredictable responses to specific insert interventions. The authors attributed these individual responses to subject specific strategies that may be influenced by mechanical factors (Bates et al., 1979; Gross et al., 1991; McNair and Marshall, 1994; Stacoff et al., 2000), neuro-physiological factors (Chen et al., 1994; Barton and Lees, 1996; Robbins and Waked, 1997; Nurse and Nigg, 1999), as well as anatomical and psychological factors.

The effectiveness of inserts/orthotics in reducing the frequency of overuse injury has been addressed in the literature with several studies reporting success in sport activities. On average, the literature reports positive outcomes for treating a variety of injuries using orthotics/inserts with reductions in injury incidence of between 70% and 80%. The effectiveness of inserts in the treatment of plantar fasciitis has been investigated by a number of researchers showing moderate success. Gross et al. (2002) investigated the use of semi-rigid foot orthotics for 15 subjects suffering from plantar fasciitis. Pain severity was assessed following a 100m walk using a visual analogue scale as well as a Foot Function Index questionnaire before the intervention and at specific dates after applying the orthotic intervention. The findings showed that the use of orthotics resulted in reduced pain ratings (both visual analogue scale and Foot Function Index) with an overall reduction in pain of 66%. Similar observations were made by Landorf et al. (2006). They investigated the effectiveness of three insert conditions (soft, thin foam; firm foam;

semi-rigid plastic) in relieving pain due to plantar fasciitis using a 12 month follow up protocol. 135 subjects were recruited and randomly provided with one of the insert conditions. Measurements of pain and function were obtained using scales of 0-100 (best-worst) after 3 months and 12 months of intervention. The results showed decreased pain scores for the firm (8.7 points) and semi-rigid insert (7.4 points) conditions compared to the firm insert with similar findings for function scores. However, these findings were not observed at the 12 month sample point, leading the authors to conclude that orthoses produced small and short-term benefits in pain reduction. Longer term effectiveness did not differ between insert conditions. In contrast to previous studies, Pfeffer et al. (1999) did not observe benefits from the use of semi-rigid orthoses. In a prospective study involving 236 subjects with plantar fasciitis, subjects were randomly assigned to one of five groups: 1) stretching only (foot and ankle); 2) stretching plus a silicone heel pad; 3) stretching plus a felt pad; 4) stretching plus a rubber heel cup; 5) stretching plus a custom plastic orthoses. Following 8 weeks of insert use and stretching exercises, subjects were assessed for pain and function using a pain scale of 0-100 (best-worst) and Foot Function Index. The findings showed a positive influence of the silicone, rubber and felt inserts compared to stretching only. These inserts were 23-9% more effective than stretching alone, whereas the plastic orthoses were 3% less effective.

The incidence of stress fractures in military recruits was studied by Simkin et al. (1989). They analyzed individual foot arch structure and the effect of a specific orthotic device. Results demonstrated that movement-related stress fracture frequencies depended on foot structure. Femoral and tibial stress fractures were more frequent in subjects with high arched feet. Metatarsal stress fractures were more frequent for subjects with low arches. The use of a semi-rigid orthotic device (Langer military stress orthotic) reduced the incidence of stress fracture only in subjects with high arches. The same orthotic reduced metatarsal stress fractures only in subjects with low arches. Finstone et al. (1999) performed a prospective study to investigate the effectiveness of custom made orthoses in reducing stress fracture incidence in infantry recruits. Injury rates were tracked for three groups: one using a soft orthosis, one using a semi-rigid orthosis and a control group. Individuals were assessed at bi-weekly intervals during 14 weeks of basic training. The findings of the study showed a reduction of stress fracture incidence of 11.3% when using the semi-rigid and 16.3% when using the soft orthoses compared to the control condition. The authors furthermore note that the soft orthoses were tolerated better by recruits. Mündermann et al. (2001) observed a reduction in stress fractures or pain at the foot of 13.4% when using the most comfortable of six boot insert conditions compared to a no insert control. Subjects were divided into two groups of 103 participants (experimental and control) and participated in four months of training, where injury occurrence was recorded using a questionnaire. Similar observations were made by Schwellnus et al. (1990) who observed a weekly injury rate of 1.4 per 1000 recruits per week for a control group of 1151 recruits and none for an experimental group of 237 randomly selected recruits using a neoprene insole. In contrast, Gardner et al. (1988) observed no reduction of stress fractures using shock absorbing polymer insoles.

Knee pain has been identified in a systematic review of the literature as the primary injury site for running (Fong et al., 2007). The effectiveness of orthotics to relieve knee pain was assessed in a study by Eggold (1981). Three hundred runners were surveyed with regard to frequency of prescription of orthotics and their ability to relieve pain. Results showed that 40% of runners were prescribed orthotics because of knee pain and that over 70% of these subjects reported 80% or higher subjective relief of pain with the orthotics. James et al. (1978) used rigid and flexible orthotics for runners with knee injuries. Of the treated runners, 78% were able to return to their previous running program. Analysis of six of the successfully treated runners found that the orthotics reduced both the maximum and the duration of foot pronation for these runners (Bates et al., 1979). However, a functional explanation of the potential link to injury was not provided by the authors.

Acute Injury Prevention

Acute injury of the lower limbs and the ankle in particular is a risk factor when participating in sports and training activities. Garrick (1977) provided an early summary of the occurrence of ankle sprain injuries for a variety of sports. The author identifies external support and shoe surface interactions as important factors in mitigating the frequency of ankle sprain occurrence, where ankle taping and high-top shoes were associated with a protective function. Robbins et al. (1995) and Stacoff et al. (1996) support the view that ankle sprains are among the most frequently reported acute injuries. Both intrinsic and extrinsic risk factors for sprains have been identified in the literature. Beynnon et al. (2002) reviewed the literature concerning these risk factors. They concluded that anatomic foot shape (pronated, supinated, or neutral) is not an adequate predictor for ankle sprain risk. This appears to be due, in part, to an insufficient classification system. When investigating risk factors for ankle injury, Kaufman et al. (1999) identified foot shape (flat feet or high arch) and restricted ankle dorsiflexion as well as increased hindfoot inversion as risk factors. This prospective study was performed using 449 NAVY SEAL trainees over a 2 year period. Foot shape was measure statically and dynamically during weight bearing and injury development was tracked by specially trained clinical personnel. Milgrom et al. (1991) identified an increased risk of sprain injury for populations with a large foot width compared to narrow feet. These intrinsic risk factors may be addressed using extrinsic interventions. For instance, bracing and taping have been shown to be effective measures to prevent sprain injury (Beynnon et al., 2002).

There is, however, little information on the effects of specific characteristics of footwear on the risk of ankle injury. Detrimental effects of footwear on sprain injury risk may be due to decreased proprioception such as reduced spatial awareness of foot position due to inhibition of the feedback from plantar cutaneous mechanoreceptors that would otherwise directly contact the ground (Robbins et a., 1995). Furthermore, increasing the lever arm from the perimeter of the foot to the axis of rotation in the ankle by wearing shoes may increase the ankle torque around the subtalar joint during a stumble (Stacoff et al., 1996). According to Siff and Verkhoshansky (1999, p.452) using running shoes always reduces proprioceptive and tactile sensitivity. Shoe construction may therefore directly affect injury risk. Curtis et al. (2008) investigated the role of a shoe “cushion column system” on ankle sprain rates in basketball players based on a common belief that heel cushioning has detrimental effects. Using an on-line survey, 230 national collegiate players, who sustained lateral ankle sprains during the 2005-2006 season, were investigated for the type of footwear worn. The results showed no significant difference in ankle sprain incidence between groups using the column system and a non-cushioned column system. The authors concluded that shoe design did not play a major role in ankle sprain incidence among this group of basketball players with no increase in injury risk due to the use of the cushioned column shoes.

Thacker et al. (1999) reviewed the published evidence for the effectiveness of various approaches to the prevention of ankle sprains in athletes. Ankle taping was observed to be an effective means to prevent ankle sprain injury. Furthermore, they concluded that there was no convincing evidence that shoe style played a role in the prevention of ankle injuries in basketball. These observations are in contrast with those by McKay et al. (2001) who observed a significantly greater risk of ankle injury for basketball players using air cell cushioned shoes. In their study of 10393 athletes (3421 male and 6972 female), a mixture of recreational (77.9%) and elite players (22.1%), they observed overall ankle injury rates of 3.85 per 1000 players. Three risk factors were identified: (1) players with previous injury were ~5x more likely to re-injure the ankle; (2) air-cell cushioned shoes resulted in a 4.3x increased likelihood of injury; and (3) no pre-game stretching resulted in a 2.6x higher risk of injury.

Pain Reduction

The use of inserts/orthotics has been advocated for the reduction of pain. Selected effects of semi-rigid plastic or fibreglass orthotics to treat knee pain, ankle pain, shin splints, and chondromalacia were assessed through a post-treatment survey (Donatelli et al., 1988). The purpose of the study was to determine the degree of pain relief, the longitudinal effects of orthotics in restoring levels of activity, and subject compliance. Fifty-three subjects, 20 males and 33 females, responded to the survey. Most subjects (96%) experienced relief from pain and 70% were able to return to previous levels of activity. Faunø et al. (1993) investigated the effects of shock absorbing heel inserts on the incidence of soreness in 91 soccer referees (48 with inserts and 43 served as controls) during a 5 day tournament. Using daily questionnaires and medical examinations it was observed that the calf, thigh, back, Achilles tendon and knee were the most common localizations of overuse symptoms. It was concluded that the use of inserts significantly reduced the incidence of soreness in the Achilles tendon, calf and back in this population. Some of these observations were supported by Shabat et al. (2005) who demonstrated the effectiveness of customized insoles in reducing pain in 58 sufferers of low back pain. A double blind prospective study, using the MILLION questionnaire, was chosen to compare insoles constructed using a computerized method to placebo insoles. The findings showed that 81% of the subjects preferred the customized insoles over the placebo insoles. Furthermore, a substantial improvement in low back pain following use of the customized insoles was observed. Average pain intensity reduced significantly when using the customized insoles only. The severity of pain also decreased significantly with 77% of subjects reporting level 5 pain and above initially, to

37.9% of subjects using customized insoles and 50% using placebo insoles. The authors concluded that customized insoles were effective in decreasing low back pain.

Maclellan and Vyvyan (1981) performed a small prospective study on Achilles tendonitis and pain beneath the heel. Nine subjects with pain beneath the heel and 14 subjects with Achilles tendonitis were prescribed visco-elastic heel inserts as a treatment intervention and patient progress was monitored at monthly intervals. The findings indicated that all patients experienced an immediate improvement in comfort. After one month no patients demanded any treatment other than the heel inserts. All but one subjects returned to full training or competition with only minimal pain symptoms remaining post-treatment. At month two, all but four subjects were symptom free, with one patient reporting symptoms after 3 months. In line with the observations by Faunø et al. (1993) these findings indicate that visco-elastic heel pad use was effective in reducing the symptoms of Achilles tendinitis as well as heel pain. Johnston and Gross (2004) observed similar results in a study on the effects of orthotic interventions on 16 subjects with patello-femoral pain and signs of over-pronation. Using the Western Ontario and McMaster osteoarthritis (WOMAC) scale of pain, it was found that pain significantly improved both two weeks and three months after the orthotic intervention.

The question of comfort and injury was further studied by Mündermann et al. (2001). In this study on comfort perception of shoe inserts and injury frequency they observed a 1.5-13.4% reduction in the incidence of stress fractures and pain for insert use compared with a control group. Following an insert comfort assessment session using six inserts with different material properties and shapes, 206 military personnel were fitted with either a customized shoe insert, perceived to be the most comfortable insert, or no insert. Average comfort ratings for all shoe inserts were significantly higher than those for the control condition. They furthermore observed that foot arch height, foot and leg alignment, and foot sensitivity were significantly related to differences in comfort ratings for the customized insert combinations.

In order to gain further knowledge on the functional effects of insole use, Crenshaw et al. (2000) performed a study on 17 healthy subjects. The aim was to identify kinematic and kinetic variables involved in the reduction of pain associated with medial compartment osteoarthritis through the use of laterally-wedged (5°) insoles. They identified a significant reduction in the external varus moment and estimated medial compartment load at the knee when using the lateral-wedged insole. The authors suggested that these changes contributed to the pain relief and improvement in function reported by patients with osteoarthritis.

Pain relief due to insole use was also investigated by Sobel et al. (2001). The effectiveness of insole customization in relieving post-work discomfort was investigated for 122 New York City Police Department officers. This cohort walked 3 miles per day on average and during the study wore customized insoles for up to 5 weeks for an average of 7 hours per day. Their findings indicated that insoles were effective in reducing tiredness in the feet at the end of the work day with 68% reduction in foot discomfort and 60% increase in comfort at work. Insole use did not affect back or leg discomfort in this study.

The aspect of insole customization was further studied by Bus et al. (2004). They investigated the effects of custom-made insoles on plantar pressures and load redistribution in 20 neuropathic diabetic patients with foot deformity. These researchers observed that custom-made insoles significantly reduced peak pressures and force-time integrals in the heel and first metatarsal head regions. In contrast increases in these variables were observed in the medial midfoot region. Therefore, custom-made insoles were more effective than flat insoles in off-loading the first metatarsal head region, but with considerable variability between individuals. Interestingly, off-loading occurred predominantly in the heel which was not considered an at risk region.

It must be acknowledged, however, that some researchers have not found positive results regarding pain reduction from insert/orthotic use. For instance, it has been demonstrated that foot orthotics may not be effective in treating or preventing patello-femoral pain syndrome (Hume et al., 2008). In their review, Hume et al. focused on the magnitude of the treatment effects and the clinical effectiveness of orthotics in the treatment and prevention of several lower limb injuries. The specific focus was on plantar fasciitis, tibial stress fractures and patellofemoral pain syndrome in relation to pain, comfort, function, and injury status. The authors concluded that the effects of orthotics for treatment of pain or injury prevention were mostly trivial. In contrast to Johnston and Gross (2004), orthotics were deemed not to be effective in treating or preventing patellofemoral pain syndrome. It was concluded that customized semi-rigid orthotics have moderate to large benefits for treating and preventing plantar fasciitis and posterior tibial stress fractures, and small to moderate effects in treating patellofemoral pain syndrome. Furthermore, prefabricated semi-rigid orthotics were deemed to have moderate beneficial effects in the treatment of foot pain and foot function. The authors comment however that there is a lack of randomized controlled or clinical controlled trials as well as a lack of information that is provided in the available literature to make a concise statement on the benefits of foot orthotic use for treatment and prevention of lower limb injury.

Conclusion

A specified aim of the Kingetics, LLC orthotics system is to "reduce injury risk by >10%". For the purpose of this literature review, injury risk was separated into repetitive strain injuries, acute injuries and pain relief. The reviewed literature shows that there appears to be some evidence in support of the use of selected orthotics for improving a range of overuse injuries and for providing pain relief. However, this evidence must be considered weak at this point due to the small number of studies and a lack of methodological consistency between the studies. Nonetheless, benefits of inserts/orthotics have been stated as 10-13% reductions with regards to overuse injuries of the foot, 10-20% for plantar fasciitis, 5% for metatarsal stress fractures and 4% for tibial stress syndrome. Furthermore, inserts/orthotics have been shown to provide substantial pain relief for a variety of conditions and anatomical locations. Specifically, pain has been reduced at the Achilles tendon, calf and lower back was reduced. However, little evidence exists on the long term benefits of such interventions. The existing literature indicates that these benefits may be limited in duration.

> **There is weak evidence in support of the use of orthotic devices to reduce overuse injury frequencies by between 4 and 20%.**
> **Pain relief may be substantial for specific anatomical sites, particularly at the feet. The duration of these benefits is currently unknown.**

With regards to acute injury it appears that no clear link has been made between injury risk and footwear construction. Heel cushioning systems have resulted in contradictory outcomes. However, shoe construction does not generally appear to have a direct impact on acute injury occurrence. Furthermore, it is not known what effect a very stiff carbon fibre insole may have on the risk of acute injury in uneven terrain. In the view of the author, due to the highly varied nature of an in-the-field military application with varied and changing surface conditions, this point requires further investigation.

> **There is little evidence linking shoe construction to acute injury development. This cannot, however, be discounted as a potential contributor for the envisioned military application.**

Specific areas of consideration for the Kingetics, LLC insole system are its potential effects on impact mitigation, stabilization and skeletal “alignment” (tibial rotation, pronation, arch support and hip abduction). The reviewed literature shows that the effects of inserts/orthotics on skeletal “alignment” are typically small and inconsistent. The effects of most mechanical adjustments are different for different subjects and the effects of specific interventions on individuals cannot currently be predicted.

> **Changes in skeletal “alignment” due to Inserts/orthotics are small and inconsistent. They do not achieve the aim of substantially and consistently influencing alignment.**

Energy

This section is concerned with the current evidence relating to the concept of reducing energy consumption and enhancing performance through the use of orthotics and inserts. One aim of the Kingetics, LLC orthotics system is to “significantly reduce oxygen consumption” by reducing shoe mass and by returning mechanical energy from the orthotic. Variables of particular interest are boot weight, level of energy return, time of energy return and prototype instability (increased muscle activity). The system aims to increase energy storage and return using the spring and lever system. The following sections will address the specified aims by reviewing the current knowledge on reducing metabolic energy demands and enhancing movement task performance through the use of alterations in shoe construction, orthotics and inserts.

Metabolic Cost of Locomotion

The effects of footwear and orthotics on metabolic demands of locomotion have been investigated in the literature. The following section summarizes the current literature on the effects of footwear/orthotics and modifications of their respective properties on the metabolic cost of locomotion in human beings.

Effect of Mass

Footwear mass has been a focal point for a number of investigations. Frederick (1984) provided an early review of the performance related effects of shoe design on the economy of locomotion and argued that the effect of carrying extra weight on the foot during running approximates a 1% increase in metabolic demand per 100g per foot. It must be acknowledged, however, that Frederick based this conclusion on the interpolation of results from several studies. In fact, no study in this review investigated the effects of incrementally increasing shoe mass by 100g. Soule and Goldman (1969) and Ralston (1981) performed their experiments by adding weights of 6 kg and 4 kg to the foot respectively. It can be expected that this will lead to substantial alterations of movement kinematics, which may make these findings less meaningful. Observations by Martin (1985) on the effects of increasing shoe mass (0.5 and 1.0 kg) on energy costs were in line with the statements by Frederick (1984). Using 15 highly trained men, the effects of load carriage on metabolic and kinematic variables during treadmill running at 12 km/h were examined. The results demonstrated that $\underline{VO_2}$ due to foot loading increased approximately 7.2% per kg of load. These observations are supported by Turner et al. (2010) who, in a study on 25 men and 25 women wearing firefighting garments and equipment, observed mean increases in metabolic and respiratory variables per 1-kg increase in boot weight of up to 5-10% when treadmill walking. Increases were, however, considerably smaller for women and 2-3% increases in oxygen consumption were observed for stair climbing. Jones et al. (1984) observed increases in VO_2 of approximately 0.5% and 0.9% per 100 g footwear mass for walking and running, respectively, at 3 distinct velocities. In that study, metabolic costs increased with gait velocity, an observation also made by Russel and Belding (1946). Further evidence in support of this relationship of energy cost and footwear mass include studies by Catlin and Dressendorfer (1979), who observed increased oxygen cost of 0.9% per 100 g mass difference per shoe, and Legg and Mahanty (1986) who observed a mean increase of 0.96% in VO_2, whilst backpacking, for each 100 g increase in boot mass. Therefore, there is a general consensus that the effect of adding additional mass to the feet during locomotion results in an increased metabolic cost in the order of 0.7% to 1% per 100 g. However, as highlighted in a review of biomechanical and physiological aspects of load carriage in soldiers by Knapik et al. (2004), the magnitude of the increase may depend on the task, gender and whether subjects are wearing additional protective clothing or equipment.

Effects of Energy Return

The concept of energy storage and return is of great interest to footwear design due to its potential performance benefits. Provided that energy is stored and returned within the correct boundary conditions for a specific movement task, benefits may be observed in terms of reduced cost of locomotion and enhanced performance. The necessary boundary conditions have been summarised by Nigg and Segesser (1992) and include: (1) the storage of energy, typically using an elastic body; (2) the return of energy, typically achieved by returning the shape of the deformed structure to its original shape at the correct amplitude (sufficiently large to affect the movement) and frequency (typically in the order of 2-5 Hz); and (3) the returned energy must be used for an improvement in performance. Stored energy must be returned in the correct location and at the correct time during the gait cycle.

One example of the beneficial effects of energy storage and return on energy expenditure includes the power disk concept (Nigg, 2010, pp. 225-227). This novel shoe concept uses a heel disk element that delays the return of energy stored in the disk to a time when the force acting on the disk is small. Effectively, the “PowerDisk” deforms when the heel touches the ground and the stored energy remains in the heel until it is returned when the heel starts to leave the ground. A pilot study using three male subjects showed that, compared to a control shoe, the PowerDisk device provided a 3.7% reduction in oxygen consumption.

Frederick et al. (1980) found a significant difference in VO_2 for a group of 11 subjects running in non-air-soled and air-soled type shoes. Air-soled shoes use an inflated air bladder imbedded in the shoe’s midsole. Interestingly, the air-soled shoes required 2.8% less VO_2 while running, despite having a slightly higher mass (mean difference 33g/pair) in comparison to the non-air-soled shoe. All other aspects of the shoe design were similar. Furthermore, Daniels et al. (1981) showed that, when compensating for shoe mass differences, air-soled shoes significantly decreased metabolic costs (difference 1.6%) when compared with an identical, non-air-cushioned shoe. In that study two different running velocities were assessed (3.83 and 4.47m/s), however significant findings were only observed for the higher running velocity.

In another study, Collins and Kuo (2005) demonstrated that an optimized foot prosthesis reduced the metabolic cost of walking when compared to a regular prosthesis. The authors associate the beneficial effects of the prosthesis to the efficient return of mechanical energy. However, no information on the mass of the device was provided.

Effect of Stiffness

The effects of shoe stiffness on energy have been investigated by Roy and Stefanyshyn (2006). The effects of adding a stiff insole to a running shoe resulted in a metabolic energy saving between 1 and 2%. During this experiment, carbon fibre plates were inserted into running shoe midsoles and running economy, joint energy, and electromyographic (EMG) data were collected from 13 subjects. Interestingly, decreases in energy consumption rates were greater for subjects with larger body mass. This may be of particular relevance when considering the application for a load carrying scenario such as a military application. The authors associated the reduced energy demands with a reduction in the loss of mechanical energy that occurs due to energy dissipation at the metatarso-phalangeal (MTP) joint. Typically, the MTP joint absorbs a substantial amount of energy, while the energy produced at this joint is small (Stefanyshyn and Nigg, 1997). As a result, in normal gait scenarios, the metatarso-phalangeal joint loses energy during each ground contact. Additionally the favourable energy results were influenced by the increased longitudinal lever produced by the stiff insoles.

Material

Nigg et al. (2003) investigated group and individual differences in oxygen consumption, together with differences in EMG activity for selected lower limb muscles during running in shoes with different mechanical heel characteristics. Twenty male runners ran using shoes that had a mostly elastic heel or a mostly visco-elastic heel. The findings indicated that changes in the heel material characteristics caused subject specific changes in oxygen consumption but that no significant effects were observable across the group of runners. Furthermore, subject and muscle specific changes in activation intensities before heel strike were observable. The functional effects of these observations, however, are currently still a point of discussion and require further investigation.

Effects of Comfort

Comfort is an important aspect of footwear construction and has been assessed in relation to shoe/insole modifications (Henning et al. 1993; Chen et al. 1994). These studies correlated subjective comfort assessments with plantar pressure measurements and the outcomes will be discussed in detail later in this review (see section 5.1). Nigg (2010, pp. 181-182) identified a relationship between perceived comfort of footwear and metabolic efficiency of running. A study was performed that identified a 1% larger oxygen consumption for subjects using what they each perceived as their least comfortable shoe in comparison to their most comfortable shoe condition. It was concluded that oxygen consumption and, therefore performance, was influenced by the subjective comfort of a shoe.

Mechanical

Improving the work-energy balance during locomotion may lead to substantial enhancements in performance. The major strategies for such improvements, according to Nigg et al. (2000), are storage and return of energy; minimizing energy loss; and optimizing muscle function. As summarised above, effective storage and return of energy during human movement requires energy storage, energy return at the appropriate amplitude and frequency, and energy return at the appropriate location and time. Examples of storage and return of energy in sports equipment are readily available and include elastic poles for pole vaulting, spring boards for diving, tuned surfaces for indoor track and field surfaces and spring floors for tumbling and gymnastics. Optimization of equipment may have substantial benefits on performance as can be seen in the example of pole vaulting: changing from aluminum poles to fibreglass poles leads to approximately a 20% improvement in performance. Similarly,, tuned indoor sport surfaces have lead to an improvement in running times of approximately 2% (McMahon and Greene, 1979).

In shoes, the question of storage and return of energy depends on the stiffness of the shoe sole, the deformation of the sole material and the return of any stored energy. The following section will address the current body of knowledge regarding the effects of stiffness, the return of energy, the effects of weight and the effects of comfort on performance.

Effects of Stiffness

Stefanyshyn and Fusco (2004) stated that, according to research (Fukunaga et al., 1978 and 1981; Chapman and Caldwell, 1983 and Ae et al, 1987), one of the critical factors affecting performance in sprinting is the ability of the sprinter to generate and absorb large amounts of mechanical energy during each ground contact. While energy absorption and production during ground contact is similar at the ankle, knee and hip joints (Stefanyshyn and Nigg, 1997), energy absorption at the metatarsophalangeal (MP) joint is substantial but energy production is minimal. These observations hold true not only for sprinting activities but have also been observed in long jumping and vertical jumping activities (Stefanyshyn and Nigg, 1998). An approach to counter this loss of energy is to increase the bending stiffness of the shoe sole.

Stefanyshyn and Nigg (2000) performed a study investigating the influence of shoe midsole stiffness on lower extremity joint power during running and jumping as well as vertical jump performance for 25 subjects, respectively. When comparing energy generation during vertical jumps and running for 5 subjects using carbon fibre plates inserted into the shoe midsole, no influence on energy generation and absorption at the ankle, knee, or hip joints was observed. Stiff shoes did not increase energy storage and reuse at the metatarso-phalangeal joint but reduced the amount of energy lost at this joint. Furthermore, vertical jump height was significantly increased (average, 1.7 cm for the group of 25 subjects) when the bending stiffness of the shoes was increased. In a study investigating the effects of stiffness on sprinting, Stefanyshyn and Fusco (2004) observed increases in performance with increased sprint shoe stiffness. A total of 34 track and field athletes ran in four different shoe conditions: their own sprint spike shoes and three different insert conditions using carbon fibre plates with different bending stiffness properties (42, 90, and 120 N/mm, determined in a three-point bending test). Three subjects produced their best performance with their own spike shoes. The majority of subjects, however, showed an improvement for at least one plate condition (stiffness condition), with a significant average improvement of 1.2% for the entire group. Responses differed between individuals, which was taken as an indication that improved performance is not only a result of reducing energy loss but that other factors may play a role (e.g. comfort and muscle strength). As such, an “optimal” stiffness does not necessarily mean using the stiffest plate. Muscles of the calf, for example, may not have been strong enough to counterbalance the increased moment produced by the stiffer plates or stiffer plates may have been uncomfortable to use, thereby restricting sprint performance.

Ferris et al. (1999) observed that, when hopping or running on different surfaces, humans adjust their effective leg stiffness to offset changes in surface stiffness. The end result of this approach is that the overall stiffness during the leg-surface interface remains independent of the surface stiffness. Ferris et al. (2006) applied this concept to the use of prosthetics. In this study, 7 subjects were instructed to hop on their left leg at 3 distinct frequencies using 2 different orthosis conditions. Condition 1 consisted of a custom-built ankle-foot orthoses with a linear extension spring. Condition 2 consisted of an ankle-foot orthoses without a spring. The findings showed that total ankle and leg stiffness did not change across the two conditions. Subjects decreased their ankle joint stiffness to offset the orthoses spring stiffness. This reduction in ankle joint stiffness was accompanied by a decrease in calf muscle activity. The authors suggested that an elastic exoskeleton might improve human running performance by reducing muscle recruitment, thereby causing a reduction in metabolic cost. It is reasonable to speculate, therefore that this approach may be used for able bodied athletes to minimize fatigue and improve performance.

Effects of Energy Return

Effectively storing and returning energy within a shoe is technologically challenging. Sufficient energy must be stored and energy must be returned at the correct time, frequency and location. Appropriate frequencies for energy return are summarised by Nigg (2010). During running, ground contact times approximate 250 ms. Therefore energy storage should occur during the first 125 ms of contact and energy release should occur during the second 125 ms of ground contact, thereby corresponding to a frequency of 2 Hz. In sprinting contact times are shorter (~100 ms), and so the corresponding loaded natural frequency of the energy storage element should, therefore, approximate 5 Hz. In jumping, given a contact time of 200 ms, the corresponding frequency is 2.5 Hz. This means that the frequency range for effective energy return in human locomotion is typically in the rage of 2-5 Hz. Orthotics or insoles have the potential to store and return energy, provided these criteria are met by the structure used. Orthotics and insoles are particularly promising because they can extend into the forefoot where energy may be returned during takeoff rather than the heel which is not a functionally important region at this point in the gait cycle.

The concept of providing efficient energy return using an insole or orthotic has been attempted by a number of researchers. However, results have generally been ineffective. Nigg (2010, pp. 225-227) provide valuable information on one shoe based energy storage and return concept (PowerDisk), shown to provide an energy return of 7% during walking. The “PowerDisk” is a device embedded in the heel of a shoe and deforms at touchdown. The energy remains stored until the heel starts to leave the ground at which time, the stored energy is returned. A pilot study was performed using three male subjects and the PowerDisk shoe was compared with an identical shoe without the PowerDisk device. The results showed that the PowerDisk shoe returned six times more energy at the heel, returned the energy at the appropriate time (at heel-off), returned energy that corresponded to approximately 7% of the total mechanical energy and reduced oxygen consumption by 3.7% during walking on a treadmill.

Effects of Reduced Weight

As discussed earlier (see section…) footwear mass can affect performance from a metabolic perspective. Similarly, footwear mass can affect mechanical energy. Martin (1985) investigated the effects of lower extremity loading on kinematic and physiological variables during running. Fifteen male subjects performed treadmill running at 3.33m/s. Five different load conditions were examined: no added load, 0.50 kg added and 1.00 kg added to either the thighs or feet. In line with the results presented previously, the investigators observed increases in $\underline{VO_2}$ with increasing foot loading of approximately 7.2% per kg of load. Furthermore, the results showed that an additional 1 kg of mass added to the feet significantly increased stride length (1.4 cm), swing time (9 ms), flight time (6 ms) and decreased peak ankle velocity (0.23 m/s). Lower load conditions did not result in significant changes in kinematic variables. Furthermore, the authors observed that significant increases in mechanical work occurred with additional loading at the foot and not at the thigh. The authors attributed the increased physiological demand directly to the mechanical work increases, which are attributed to the increased inertia of the loaded segments rather than kinematic changes.

Conclusion

One of the aims of the Kingetics, LLC orthotics system is to “significantly reduce oxygen consumption” using a combination of reduced shoe weight and energy return from the orthotic. There is general agreement in the literature that reducing the mass of footwear results in a reduced metabolic cost that approximates 0.7 to 1.0% per 100g.

> **Reducing footwear mass reduces metabolic cost by 0.7-1.0% per 100g reduction during walking.**

Further reductions in the metabolic cost of locomotion have been documented for energy storage and return, and heel cushioning devices. As such, energy savings have been reported in the range of 1.6-3.7%. The effectiveness of such devices is highly dependent on the movement task (e.g. walking or running) and the storage and return of energy within the boundary conditions summarized below. Thus far, little evidence exists for systems that successfully reduce the metabolic cost of locomotion.

> **Metabolic costs may be reduced using footwear interventions. However, such systems must operate within movement specific boundary conditions.**

Further parameters that may affect metabolic cost include insole/orthotic stiffness and comfort. Stiffer soles have reduced the metabolic demands of running by 1% with better results observed for heavier subjects. It is currently not known whether such a result may be observed in walking; however the impact of body mass may be particularly relevant for a military load-carrying scenario. Similar metabolic savings were observed when individuals used the insole condition that they perceived as the most comfortable when compared to the least comfortable insole condition for running, thereby indicating a metabolic benefit from comfortable footwear.

> **Metabolic demands of walking and/or running may be positively influenced by utilizing stiffer insole materials or increasing the comfort of the footwear.**

Insole stiffness was also observed to affect performance. Sprinting times were reduced and jump height increased when using stiffer insoles by reducing energy loss at the midfoot. However, an single optimal stiffness does not appear to exist. Individual solutions appear to be necessary to address task and subject-specific limitations; for instance, regarding muscle strength and perceived comfort.

> **Stiffer insoles enhance sprinting and jumping performance by reducing energy loss at the midfoot and by increasing the longitudinal lever of the shoe sole.**

Storage and return of energy using an insole/orthotic device is generally difficult to achieve and, using current EVA and PU materials, results in small gains (< 1%). Sufficient energy must be stored and returned at the appropriate time (the second half of the foot-ground contact), frequency (2-5Hz) and location (the forefoot). Orthotics or insoles have the potential to store and return energy, provided they are constructed to deform and return energy at the heel and forefoot, respectively. Energy returns of 7% have been observed.

> **Using current insole material technologies, only little energy return is feasible. Alternative materials and orthotic/insole construction may lead to substantially greater and functionally relevant returns of energy. However, this has not yet been demonstrated in a product.**

Comfort

Another aim of the Kingetics, LLC orthotics system is to "increase comfort ratings for the Kingetics, LLC system by 10% over traditional combat boots". Comfort is an important aspect of footwear construction that, as shown in the sections above, may affect both injury prevention and performance. The following section is concerned with the current evidence relating the use of shoes, insoles and orthotics to the perception of comfort. Variables of particular interest are foot-orthotic points of friction, high pressure areas on the bottom of the foot and their influence on skeletal alignment. The following sections will review the current evidence regarding the ability of inserts and orthotics to exert a positive influence on these aspects.

Pressure

Pressure distribution between the foot and the shoe has been the focus of a number of investigations with regard to its relationship with comfort or associated variables. Studies on the effects of foot abnormalities have shown a general increase in a number of plantar pressure variables. Stokes et al. (1975) showed a lateral shift of the highest maximum load on the forefoot and a decrease in the load carried by the toes for diabetic patients. In subjects with ulcers, maximum loads were exerted at the site of the ulcer. These findings are supported by Ctercteko et al. (1981) who investigated vertical forces in walking for subjects with diabetes, using a pressure plate containing 128 load cells. Here, diabetic patients with neuropathy transmitted less force through the toes with a medial shift of the force at the metatarsal heads and ulcers typically occurred at the site of maximum loading. Furthermore, the absolute force at the site of maximum loading was significantly greater in subjects with ulcers. The findings by Stokes and Ctercteko are supported by Boulton et al. (1987) who studied foot pressures for 44 diabetic subjects without neuropathy. They observed abnormally high pressures under the metatarsal heads and a reduction in the ratio of toe to metatarsal head loading for sixteen diabetic subjects. Soames (1985) compared peak pressure and temporal parameters for 21 men and 11 women when walking barefoot and shod. Shod walking appeared to induce a change in pressure distribution in the forefoot and increased contact times for the toes. During shod walking, peak pressures increased medially along metatarsal heads, whereas pressure was more evenly distributed in barefoot walking.

The above findings indicate that pressure distribution under the foot is associated with the ability to perceive pressure and, consequently, the health of the foot. It has also been observed that the use of footwear affects the mechanics of the interaction of the foot with the ground. It was speculated that pressure distribution at the foot when wearing shoes is associated with comfort. Henning et al. (1993) and Chen et al. (1994) investigated the effect of insole modifications on perceived comfort and pressure distribution under the foot. Henning et al. (1993) did not directly address comfort, but identified a linear relationship between pressure variables and ‘perception of cushioning’ scores. Here, plantar pressure increased with increasing shoe hardness. A limiting factor of this study was the use of a limited number of pressure transducers (eight) as well as the use of shoes that, according to the authors, did not represent a realistic hardness range. Chen et al. (1994) used four pairs of insoles, differing in design, and 14 male subjects walking and running on a treadmill. Plantar pressures were measured using a pressure-measuring insole. The results of this investigation indicated that walking in the most comfortable insole caused a shift of the pressure from forefoot to midfoot, thereby providing a more even distribution of pressure. For running, lower pressure in the medial forefoot area could be observed. The authors concluded that the pressure distribution between the plantar surface of the foot and the shoe could predict the change of shoe comfort and may therefore be important for understanding shoe comfort. These observations were expanded upon by Jordan and Bartlett (1995) who investigated the relationship between short-term perceived comfort and pressure distribution on both the dorsal and plantar surfaces of the foot during walking. 15 healthy male subjects performed walking trials using a range of commercially available casual footwear. Perceived ratings of upper and plantar comfort were measured using a specially designed questionnaire. Dorsal and plantar pressure distributions were measured using a pressure-measuring sensor pad and insole, respectively. Their findings support those reported by Henning et al. (1993) and Chen et al (1994). Increased total plantar force and force-time integral were to related to a decrease in perceived plantar comfort. However, overall peak plantar pressure, the pressure-time integral, and total plantar area were not related to plantar comfort. Contrastingly, for the shoe upper, it was observed that decreases in dorsal force and pressure related to decreased upper comfort. Similar effects on pressure distribution were observed by Chen et al. (1995) with respect to sensory feedback. The effects of 4 sensory input conditions during treadmill walking and running on pressure distributions were investigated. Pressure distributions for 10 subjects were measured using a pressure-insole system. The results showed that increased pressure in the midfoot area and decreased pressure in the toe area were associated with increased sensory inputs.

The effects of orthotics on pressure distribution may be related to orthotic shape. Although there is little evidence regarding the effects of orthotic shape, orthotics are typically customized to fit the needs of individuals. Bus et al. (2004) studied the effects of custom-made insoles on plantar pressures and load redistribution in neuropathic diabetic patients with foot deformity. In their study, 20 neuropathic diabetic subjects performed walking trials in flat or custom-made insoles. The findings showed that custom-made insoles were more effective than flat insoles in reducing regional peak pressures, particularly at the first metatarsal head. There was, however, considerable variability in the response of individual subjects with equal subject numbers showing successful, moderate or no effect. In addition, most pressure reductions occurred at the heel, which is not considered to be a site at risk for ulceration in this group.

Other influencing factors

In addition to pressure, a number of footwear properties concerning the perception of repeated impacts may be associated with comfort. Milani et al. (1995) studied perceived ratings and biomechanical variables of shock, pressure and rearfoot movement during running. Their findings indicated that, at the group level, the perception of more severe impacts, higher pressures and greater foot instability were strongly correlated to respective biomechanical variables. However, individual subjects generally did not appear to use these biomechanical variables to quantify impact severity. The authors suggest that the variability of individual responses may have been due to the complexity of the movement task, shifting attention away from the perception task, the use of other stimuli for impact severity assessment and the potential adaptation of kinematics or perception due to conditions prior to biomechanical assessment.

Further biomechanical variables and shoe characteristics were assessed by Miller et al. (2000). 18 subjects were recruited to assess athletic shoe comfort during standing, walking and running. The findings indicated functional groupings, whereby one shoe seemed suited for a small group of subjects and another shoe was generally comfortable for a large group. Furthermore, comfort decreased from standing to running conditions. Skeletal alignment, specifically eversion angle, was observed to be related to comfort for one shoe. The authors concluded that comfort is activity dependent and that the fit of the shoe is not a sufficient measure for comfort. Skeletal alignment as well as shoe torsional stiffness and cushioning may, therefore, be regarded as important variables for comfort.

Mündermann et al. (2001) conducted a study to determine lower extremity anthropometric and sensory factors in relation to comfort perception of shoe inserts. 206 military personnel were supplied with six inserts that differed in arch and heel cup shape, hardness, and elasticity in the heel and forefoot regions. Measurements of foot shape, foot and leg alignment, and tactile and vibration sensitivity of the plantar surface of the foot were taken. Footwear comfort was assessed using a visual analog scale which has been validated as a reliable assessment tool (Mündermann et al., 2002). The findings showed that foot arch height, foot and leg alignment, and foot sensitivity were significantly related to differences in comfort ratings for the hard/soft, the viscous/elastic, and the high arch/low arch insert combinations. In line with the observations by Miller et al. (2000) and Milani et al. (1995) subject specific characteristics were found to influence comfort perception of shoe inserts.

Mills et al. (2011) further examined the influence of orthoses contouring (shape) and hardness on ratings of perceived comfort. Twenty subjects were consecutively allocated to two different experiments, measuring the comfort of four prefabricated orthoses. The authors used visual analogue scales and ranking scales, respectively and measures were taken during both walking and jogging. Their findings indicated that a soft-flat orthosis was more comfortable than contoured orthoses, specifically with respect to overall comfort and arch cushioning. Orthoses comfort again differed due to movement task. The authors concluded that healthy subjects prioritize the shape of the orthosis over its' hardness when judging comfort.

Conclusions

Comfort is an important aspect of footwear. Comfort is associated with performance, injuries, muscle activity, and other biomechanical, physiological, and/or psychological factors. While comfort can be readily identified on a subjective level, it is difficult to define and/or to quantify comfort directly (Cavanagh, 1980; Slater, 1985). The section above showed that comfort has been associated with plantar pressure distribution, where the most comfortable conditions resulted in a more even distribution of pressure across the plantar surface of the foot. This in turn may be beneficial for reducing the occurrence of ulceration in pathological populations.

> **Comfortable footwear conditions lead to a more even distribution of pressure on the plantar surface of the foot.**

Comfort is also affected by rearfoot movement, foot and leg alignment and foot sensitivity. The perception of comfort is largely dependent on subject specific characteristics indicating that a range of footwear solutions may be required for the purpose of achieving optimal comfort. Measurement of comfort should be performed using a comparative measurement approach, which has been shown to be more reliable. Despite these studies, the current knowledge base and understanding of comfort and comfort-related questions is small and more research is needed to understand this concept.

> **Comfort is dependent upon a number of variables and highly dependent on the individual.**

Predicted effects of Kingetics, LLC system

Injury

The speculated effect of the new insole/sole design of the Kingetics LLC system design with respect to injuries could be in the reduction of the levers that often characterize military boots. The Kingetics LLC system can be constructed within the military boot in a way that the levers are small and the corresponding loading due to large levers is minimized. A reduction in knee and hip moments may lead to the desired effect of reducing pain or injury rates.

Energy

The Kingetics LLC system has two potential factors that may affect the energy balance positively, the heel system and the forefoot system. Most previous attempts of energy saving shoe constructions concentrate only on one part. By doing this, the potential to be successful is reduced. The energy is often returned at the wrong time, the wrong location with the wrong frequency. The proposed system may overcome this shortcoming of the previous constructions and actually provide energy savings.

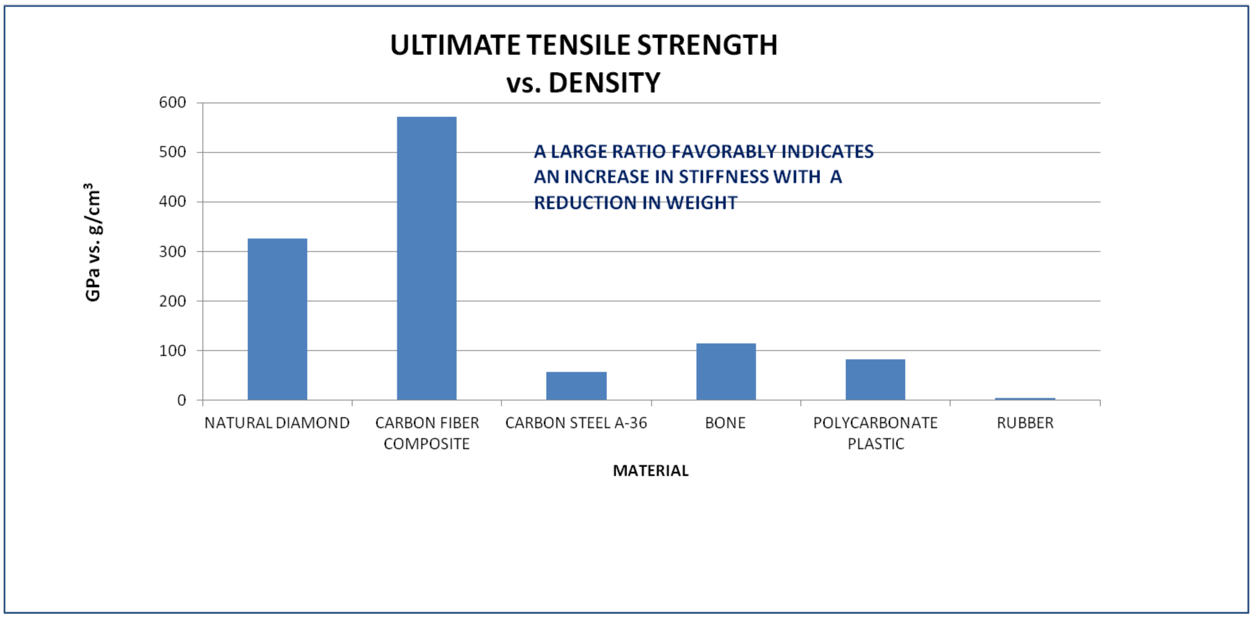
Comfort

Comfort is the result of construction and is a logical consequence of shoes that are constructed properly from a loading (injury) and from an energetic point of view. Thus, if the shoe is constructed as suggested it is likely that comfort is high and acceptance of such a product by military personal is positive. Lastly, it may be that two versions of the device may be constructed, in order to provide subjects with a choice with respect to comfort, without sacrificing any of the injury reduction or energy-return benefits.

Appendix C: Mechanical Advantage Materials Chart and Table

Table C1: Common Materials and Properties

MATERIAL	ULTIMATE TENSILE STRENGTH (MPa)	DENSITY (g/ cm3)	MODULUS OF ELASTICITY (GPa)	STIFFNESS TO WEIGHT RATIO
NATURAL DIAMOND	1048	3.21	703	326
KINGETICS SPRING PLATE/ CARBON FIBER COMPOSITE	760	1.33	67.5	571
CARBON STEEL A–36	448	7.83	206	57
BONE	172	1.49	14	115
POLYCARBONATE PLASTIC	68	0.83	2.3	82
RUBBER	7	1.38	0.03	8



ULTIMATE TENSILE STRENGTH
vs. DENSITY

A LARGE RATIO FAVORABLY INDICATES AN INCREASE IN STIFFNESS WITH A REDUCTION IN WEIGHT

Figure C1: Comparisons of Ultimate Strength versus Density

Appendix D: Puncture Resistance Testing

Report, Puncture Resistance Testing, 6 and 9 Mar 2012

Executive Summary

Puncture resistance testing IAW ASTM 2412-5 was conducted on specimens of the Kingetics orthotic and on specimens of commercially available, regulation military boot sole assemblies over two separate days of testing. The Kingetics orthotic was tested in two parts, the Spring Plate and the Heel Cradle. The military boot assemblies were prepared by separating the upper portion of the boot from the sole assembly.

The Kingetics Orthotic Spring Plate puncture resistance averaged approximately three times more than the military boot sole assemblies. The Sport Model Heel Cradle puncture resistance averaged approximately five times more than the military boot sole assemblies. The Safety Model Heel Cradle puncture resistance averaged approximately ten times more than the military boot sole assemblies.

Additional testing indicated that the puncture resistance of the entire Spring Plate was consistent across the entire plate, not just in the test area in the center of the specimen, as narrowly defined by the ASTM.

Purpose

The purpose of this testing was to document the puncture resistance of the Kingetics orthotic, in two models, Sport and Safety. A further goal was to compare the orthotics' puncture resistance with that of standard issue, commercially available, military footwear. The American Society for Testing and Materials (ASTM) 2412-05, *Standard Test Methods for Foot Protection*, was used as the reference document for this testing process.

Equipment and Test Setup

All testing was conducted at the Composite and Polymer Experimentation (CAPE) Laboratory, South Dakota School of Mines and Technology (SDSM&T), Rapid City, SD, on two separate days, 6 and 9 Mar 12. The dates of the testing were based upon the availability of the required instrumentation, equipment, and technical support to conduct the tests.

The test probe and specimen test fixture were constructed IAW ASTM 2412-5 specifications by an engineer at the CAPE Lab. The test probe and fixture were all designed to fit the test device: the MTS 810 system, the load frame, its related hydraulics, and computerized controls.

Test Narrative

The computerized test equipment protocol was set up for the test by an engineer at CAPE Lab. The actual testing was conducted by a CAPE technician. The use of the test protocol allowed the puncture resistance testing to be repeated over and over again, using exactly the same settings each time, all IAW the ASTM specifications.

The specimens to be tested consisted of the orthotics developed by Kingetics, in two models, the Sport and the Safety models. It is noted that the two models differ in the construction of the Heel Cradle only, and that the Spring Plate in both models is of the same construction.

In addition to the tests on the orthotics, puncture resistance testing was performed on regulation, standard issue, and commercially available military footwear. The specific manufacturer was Belleville, and the model tested was the DES 390, in three different boot sizes. The boots were prepared for the testing by cutting away the upper portion of the boot from the sole assembly, so that just the sole assembly was secured to the test fixture and tested.

The test process began by placing the specimen on the test fixture's bed and clamping it down. The computerized controls were then used to start the test sequence. The test probe was lowered at the appropriate rate IAW the ASTM and the applied force (in Newtons) was measured and recorded. The distance that the probe was extended was also recorded (in mm). Each trial's data was captured automatically by the instrumentation and later downloaded as text files for further processing and review. Each specimen tested had a unique test code, and therefore, so did each penetration trial.

Each trial was recorded as a set of time elapsed, applied force, and probe extension measurements. The instrumentation which measured the applied force also compared and analyzed the readings. The purpose of the comparison was to find and record the "minimum force required for puncture to occur" (Para 11.6, ASTM 2412-5). This occurrence was further defined as the applied force necessary so that the probe tip was extended through the specimen and the full diameter of the probe completely penetrated the specimen. This was interpreted and recorded by the instrumentation when the applied force rapidly decreased by one-half the force measured. A review of the amount of probe extension, along with a comparison of the thickness of the specimen, confirmed that the test probe was penetrating the specimen IAW the ASTM.

Two sets of graphs can be developed and analyzed using the data recorded by the instrumentation. The first set is the detailed track of the probe, measured by applied force (in Newtons) and by the amount of probe extension (in mm). The peak of the graph represents the "minimum force required for penetration to occur". The second set of data is the cumulative recording of “minimum force required”, by specimen penetration trial. The second set of data may best be described as a summary of all the penetration trials made on each specimen.

The second set of data, the summary set, is most appropriate for use in this report. The first set of data, the detailed set, requires additional analysis and may be useful in any forthcoming report. Only a representative sample of the graph generated by the detailed data set is provided for this report, as background information only.

The testing was conducted over two days at the CAPE Lab, 6 and 9 Mar 12. Additional follow up testing may be required and will be scheduled at a later date. The first day of testing provided more penetration trials per specimen, but was limited in the number of specimens tested. The second day of testing limited the number of penetration trials to the minimum requirements of the ASTM, but allowed the completion of all the desired testing on each specimen for all tested specimens.

The ASTM requires that the penetration trials not be placed within one inch of the edge of the specimen. This restricts the placement of the penetration trials to an area roughly in the center of each specimen. The appropriate limits were marked on each specimen and the tests were conducted IAW the ASTM. This restriction applied to both the orthotic specimens and the boot sole specimens and this group of testing was called Part 1 of the testing.

It was observed that the orthotics’ Spring Plate construction was consistent all across the entire orthotic and that the puncture resistance should not differ whether conducted inside or outside of the restricted testing area as prescribed by the ASTM, or within the one inch margin of the orthotic’s edge. This same observation was made of the Heel Cradle. These observations resulted in Part 2 of the puncture resistance testing. Part 2 testing consisted of limited testing outside the limited area prescribed by the ASTM and within the one inch margin of the specimen edge. The purpose of Part 2 of the testing was to document the presence or absence of any degradation of puncture resistance at the edges of the orthotics. Part 2 testing was conducted only on the orthotics and not on the boot sole specimens.

During the testing process, it was observed that the test probe was jeopardized when applied against the fulcrums of both the Spring Plate and the Heel Cradle. In the case of the Spring Plate fulcrum, the test probe had difficulty finding purchase on the smooth, rounded surface. The concern was that the probe would slip off the fulcrum’s surface and either bend or break. In the case of the Heel Cradle, the probe was able to penetrate the fulcrum, but, in one case, the fulcrum split off a fragment of the fulcrum. In a second trial, the fulcrum was completely split off the Heel Cradle.

When testing the Safety Heel Cradles, it was noted that the test probe was able to penetrate the material, but the process was slower and more difficult than with the thinner and lighter Sport Model Heel Cradle.

Based the time constraints due to equipment and personnel availability, the difficulties experienced with the fulcrums and the Safety Heel Cradles, and the need to complete all of the testing, any further testing of the fulcrum and the Safety Heel Cradles was suspended for this series of testing.

On 6 Mar 12, Part 1 of the testing, the ASTM-prescribed penetration trials, were performed on two Sport Model sets of orthotics. On 9 Mar 12, Part 1 of the testing was completed on the remaining one set of Sport Model orthotic, three sets of Safety Model orthotics, as well as the three sets of boot soles. Part 2 of the testing was completed on a limited number of orthotics.

A series of photographs were taken throughout the testing process to document the instrumentation, equipment, and handling of the specimens.

Figure 1: The MTS 810 Hydraulic Test Frame

Figure 2: The test fixture, on which the test specimen is mounted

Figure 3: The Hydraulics Controller

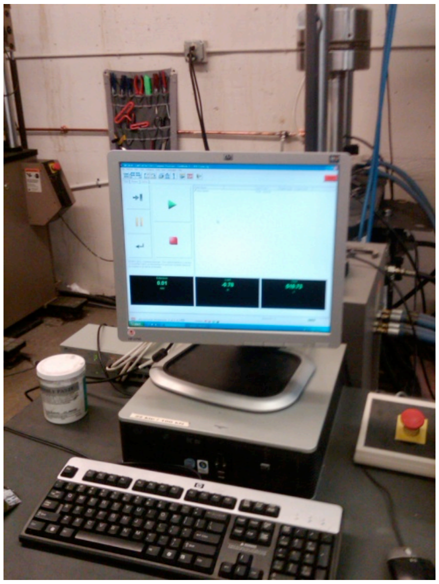


Figure 4: The computer test control station.

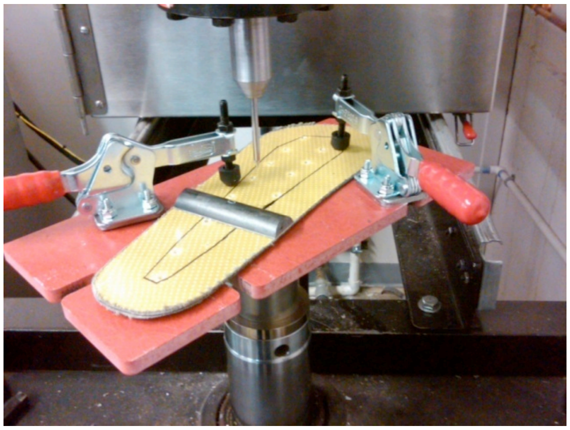


Figure 5: The Spring Plate, locked onto the test fixture, with several trials completed

Figure 6: The Heel Cradle, locked onto the test fixture, with several trials completed

As shown in Figures 5 and 6, the test specimens were mounted in the MTS 810 test fixture and puncture testing on the specimens was conducted. Each hole in the specimen represents a penetration trial. The area outlined in black on the Spring Plates and in white on the Heel Cradles represents the area prescribed by the ASTM in which testing may be conducted. This testing was called Part 1 testing. Part 2 testing consisted of penetration trial outside the marked areas, and within the one inch margin from the specimens' edges.

Test Results

Figures 7 and 8 show test specimens with the penetration trials completed.

Figure 7: The Spring Plate

Figure 8: The Heel Cradle

The test narrative reported issues with testing the fulcrums on both the Spring Plates and on the Heel Cradles. Specifically, the fulcrums either broke in pieces or broke completely off the test specimen. Figures 9 and 10 serve to document these issues on the Heel Cradles.

Figure 9: A sliver has broken off the fulcrum as a result of the penetration trial

Figure 10: The fulcrum has separated from the Heel Cradle completely

As stated in the test narrative, the tests involving the fulcrums were terminated to preclude any damage to the test probe.

As reported in the test narrative, the computerized test protocol identically reproduced the penetration trials repeatedly. A detailed data set was generated for each penetration trial. Figures 12 and 13 are representative samples of the detailed data set.

Figure 12: Exemplar detailed penetration trials 1 through 7 on a left Spring Plate (Sport Model)

Figure 13: Exemplar detailed penetration trials 8 through 14 on a left Spring Plate (Sport Model)

Additionally, a summary data set was generated for each specimen, capturing the "minimum force necessary" to puncture the specimen. Figures 14 through 16 are examples of the summarized penetration trial results, including Spring Plates, Heel Cradles, and Boot Sole Assemblies.

Figure 14: Example Summary Chart, Spring Plate penetration trials

Figure 15: Example Summary Chart, Heel Cradle penetration trials

The boot sole assemblies were tested in the same manner as the Kingetics orthotics, using the same testing protocols and equipment.

Figure 16: Example Summary Chart, Boot Sole Assembly penetration trials

Additionally, a summary data set was generated for each specimen, capturing the "minimum force necessary" to puncture the specimen. Figures 17 through 18 are examples of the summarized Part 2 penetration trial results, including Spring Plates and Heel Cradles.

Figure 17 documents what is believed to be an error in sample marking. The specimen labeled "SAF1RH1" is the only penetration trial of a Safety Model Heel Cradle made before cancelling further testing of the Safety Model Heel Cradles to preclude damage to the test probe. The specimens marked "SAF2LH1" and "SAF2RH1", respectively, are actually Sport Model Heel Cradle Part 2 penetration trials, and were incorrectly marked prior to the testing. This marking error will be corrected in future testing. The data itself is deemed to be correct for a Sport Model Heel Cradle.

Figure 17: Example Summary Chart, Heel Cradle, Part 2 penetration trials

Figure 18: Example Summary Chart, Spring Plate Part 2 penetration trials

Table 1: Summary of Puncture Resistance Testing Results, Kingetics Orthotics and Commercial Military Boot Sole Assembly, 6 and 9 March 2012

Test Specimen	Type Test	Date of Test	Number of Trials	Average Applied Force (Newtons)
Safety/Sport Spring Plate	ASTM Standard	6 Mar 12	55	1861.49
Safety/Sport Spring Plate	ASTM Standard	9 Mar 12	18	1769.12
Safety/Sport Spring Plate	**ASTM Standard**	**Both Test Days**	**Average**	**1815.31**
Safety/Sport Spring Plate	Part 2	9 Mar 12	18	1706.32
Sport Heel Cradle	ASTM Standard	6 Mar 12	34	2991.41
Sport Heel Cradle	ASTM Standard	9 Mar 12	7	3138.86
Sport Heel Cradle	**ASTM Standard**	**Both Test Days**	**Average**	**3065.14**
Sport Heel Cradle	Part 2	9 Mar 12	4	2923.80
Safety Heel Cradle	ASTM Standard	9 Mar 12	4	6897.08
Military Boot Sole Assembly	ASTM Standard	9 Mar 12	9	665.69

Conclusions

As shown in Table 1, the applied force for the Spring Plate in both the Safety and Sport Models averaged approximately 1815 Newtons. The applied force for the Sport Model Heel Cradle averaged approximately 3065 Newtons. The applied force for the Safety Model Heel Cradle averaged approximately 6897 Newtons.

Also as shown in Table 1, the Part 2 testing (the tests outside the ASTM test area) results were consistent with the ASTM results, but slightly lower.

The applied force for the military boot sole assemblies averaged approximately 665 Newtons.

The Kingetics orthotic Spring Plate puncture resistance exceeded the military boot assembly by approximately three times, while the Sport Model Heel Cradle and the Safety Model Heel Cradle puncture resistances exceeded the military boot sole assembly by approximately five times and ten times, respectively.

Future Testing Requirements

While it is felt that the amount of testing conducted during the two days of testing is sufficient to support the conclusions discussed above, additional, follow up testing may be required. The testing of the Safety Model Heel Cradles must be repeated to confirm the completed test results. This will be done after some review of the testing procedure to preclude damage to the test probe. Therefore, additional testing may include, but is not limited to: additional testing of the Heel Cradles for both the Safety and Sport models; additional testing of the boot soles; and supplemental testing of the fulcrums on both the Spring Plate and the Heel Cradle of the orthotic.

It may also be necessary to test additional samples of alternate materials and compare the results of those tests against the tests of orthotics made with the current materials.

Report, Puncture Resistance Testing, 12 May 2012

Executive Summary

Additional puncture resistance testing IAW ASTM 2412-5 was conducted on one specimen of the Kingetics orthotic Safety Heel Cradle and on three specimens of laminated Spectra® composite material.

Two of the Spectra® composite material samples were similar in thickness to the Kingetics orthotic Spring Plate, and the puncture resistance was measured at 880 and 914 Newtons, respectively. The third Spectra® sample was similar in thickness to the Safety Heel Cradle and the puncture resistance was measured at 3730 Newtons.

The Safety Model Heel Cradle puncture resistance was measured at 12615 Newtons. Only one measurement was possible, since the process damaged the test probe, and the testing was suspended. Even though the measurement is reported here, the value must be discounted as not valid due to the performance of the test probe.

By comparison, in previous testing, the puncture resistance had been measured as: Kingetics Spring Plate: 1815 Newtons; Sport Heel Cradle: 3065 Newtons; Safety Heel Cradle: 6897 Newtons; and standard military footwear soles: 665 Newtons.

Conclusion from 12 May testing: The Spectra® material exceeded the puncture resistance of the military boot sole assemblies, but did not exceed puncture resistance of the composite materials used in the Kingetics orthotics.

Purpose

The purpose of this additional testing was to further document the puncture resistance of the Kingetics orthotic Safety Heel Cradle and to test the Spectra® composite material. The American Society for Testing and Materials (ASTM) 2412-05, *Standard Test Methods for Foot Protection*, was used as the reference document for this testing process.

Equipment and Test Setup

Testing was conducted at the Composite and Polymer Experimentation (CAPE) Lab, South Dakota School of Mines and Technology (SDSM&T), Rapid City, SD, on 12 May 2012.

The test probe and specimen test fixture were constructed IAW ASTM 2412-5 specifications by an engineer at the CAPE Lab. The test probe and fixture were all designed to fit the test device: the MTS 810 system, the load frame, its related hydraulics, and computerized controls.

Test Narrative

The computerized test equipment protocol was set up for the test by an engineer at CAPE Lab. The actual testing was conducted by a CAPE technician. The use of the test protocol allowed the puncture resistance testing to be repeated over and over again, using exactly the same settings each time, all IAW the ASTM specifications.

The testing process was fully documented in the original test report and was exactly duplicated during these follow up tests. The details are not repeated in this test follow up report.

The specimens to be tested consisted of the Safety Heel Cradle from the orthotics developed by Kingetics, and three specimens of plates comprised of Spectra® composite material, laminated with epoxy under pressure.

Two sets of graphs can be developed and analyzed using the data recorded by the instrumentation. The first set is the detailed track of the probe, measured by applied force (in Newtons) and by the amount of probe extension (in mm). The peak of the graph represents the "minimum force required for penetration to occur". The second set of data is the cumulative recording of "minimum force required", by specimen penetration trial. The second set of data may best be described as a summary of all the penetration trials made on each specimen.

The second set of data, the summary set, is most appropriate for use in this report.

The testing was conducted on one day at the CAPE Lab, 12 May 12. No additional testing is anticipated in support of this Phase I effort.

During the initial testing process conducted in March, it was observed that the test probe was jeopardized when applied against the fulcrums of both the Spring Plate and the Heel Cradle. Additionally, when testing the Safety Heel Cradles, it was noted that the test probe was able to penetrate the material, but the process was slower and more difficult than with the thinner and lighter Sport Model Heel Cradle. The test probe also slipped on the material, placing the probe in danger of being bent and rendered unusable. For this reason, the Spectra® material was tested first, before attempting further tests on the Heel Cradle.

As anticipated, the test probe had difficulty penetrating the Safety Heel Cradle and then became stuck in the test sample. In fact, the test probe was pulled from its holder in the test apparatus prior to being pulled from the Heel Cradle material, and the testing was suspended after one trial. The test probe will have to be redesigned and/or strengthened prior to any additional testing of Safety Heel Cradles. No additional testing is anticipated during this Phase I effort for this reason.

Because the test probe was compromised during the testing of the Safety Heel Cradle, the results from that test were discounted and were considered as not valid. For this reason, no graphs of this portion of the testing are included in this report.

After the testing of the Spectra® Sample #2, it was noted that trials 1 and 5 were placed too close to the edge of the sample, where the material was not as well laminated. Those two values were discounted when calculating the average applied force for penetration.

Table 1 represents a summary of all puncture resistance testing, for all samples.

As stated above, the same instrumentation was used for this testing and the photographs are reproduced to document the instrumentation and equipment. The test specimens were mounted in the MTS 810 test fixture and puncture resistance testing on the specimens was conducted.

Figure 1: The MTS 810 Hydraulic Test Frame

Figure 2: The test fixture, on which the test specimen is mounted

Figure 3: The Hydraulics Controller

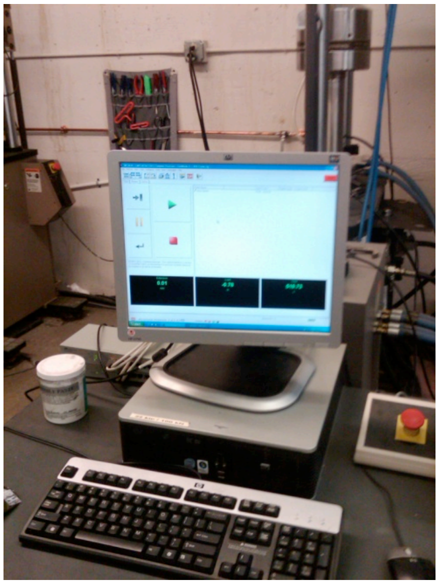


Figure 4: The computer test control station

Test Results

As reported in the original test narrative, the computerized test protocol identically reproduced the penetration trials repeatedly. A detailed data set was generated for each penetration trial. Figure 5 is representative of the detailed data set.

Figure 5: Exemplar detailed penetration trials 1 through 6 on a Spectra® sample

Additionally, a summary data set was generated for each specimen, capturing the “minimum force necessary” to puncture the specimen. Figures 6 through 8 are the summarized penetration trial results for the three Spectra® samples.

Figure 6: Summary Chart, Spectra® Sample #1puncture resistance trials

Figure 7: Summary Chart, Spectra® Sample #2 puncture resistance trials

Figure 8: Summary Chart, Spectra Sample #3 puncture resistance trials

Table 1: Summary of Puncture Resistance Testing Results, 12 May 2012, and comparisons of test results with Kingetics Orthotics and Commercial Military Boot Sole Assemblies, 6 and 9 Mar 12

Test Specimen	**Type Test**	**Date of Test**	**Average Applied Force (Newtons)**
Spectra® Sample 1	ASTM Standard	12 May 2012	880
Spectra® Sample 2	ASTM Standard	12 May 2012	914
Spectra® Sample 2	ASTM Standard	12 May 2012	3730
Safety Heel Cradle	ASTM Standard	12 May 2012	12615 (discounted)
Previous Testing	**Results**	**For Comparison**	**Purposes**
Spring Plate	ASTM Standard	6 and 9 Mar 12	1815
Sport Heel Cradle	ASTM Standard	9 Mar 12	3065
Safety Heel Cradle	ASTM Standard	9 Mar 12	6897
Military Boot Sole Assembly	ASTM Standard	9 Mar 12	665

Conclusions

As shown in Table 1, the applied force for the Spring Plate in both the Safety and Sport Models averaged approximately 1815 Newtons. The applied force for the Sport Model Heel Cradle averaged approximately 3065 Newtons. The applied force for the Safety Model Heel Cradle averaged approximately 6897 Newtons.

The Spectra® material tested at 880, 913, and 3730 Newtons of applied force, respectively.

The applied force for the military boot sole assemblies averaged approximately 665 Newtons.

Conclusion from the previous testing: **<u>The Kingetics orthotic Spring Plate puncture resistance exceeded the military boot assembly by approximately three times, while the Sport Model Heel Cradle and the Safety Model Heel Cradle puncture resistances exceeded the military boot sole assembly by approximately five times and ten times, respectively.</u>**

Conclusion from 12 May testing: **<u>The Spectra® material exceeded the puncture resistance of the military boot sole assemblies, but did not exceed the puncture resistance of the composite materials used in the Kingetics orthotics.</u>**

Future Testing Requirements

No future puncture resistance testing is anticipated during this Phase I effort. The Spectra® material remains as a material of interest that may be reviewed during Phase II testing efforts, if funded.

Appendix E: Flammability Testing

Final Report, Flammability Testing, 14 - 30 May 2012

(NOTE: This report is provided here in a truncated version. The full test report was submitted in the May 2012 Monthly Report.)

Executive Summary

Both the vertical and horizontal burn testing was successfully completed for the Kingetics orthotic, including the Spring Plate and the Heel Cradle in both the Sport and Safety Models.

The horizontal flammability rating is "HB"; the vertical flammability rating is "V-0".

Purpose

The purpose of this testing effort was to document the flammability rating of the Kingetics orthotics, for both the Sport and Safety models.

Equipment and Test Setup

UL 94, *Test for Flammability of Plastic Materials for Parts in Devices and Appliances*, 29 Oct 96, was used as the basic reference. Several other documents published by The American Society for Testing and Materials (ASTMs), were used as specific reference documents for this testing process.

Testing was conducted at the Composite and Polymer Experimentation (CAPE) Lab, South Dakota School of Mines and Technology (SDSM&T), Rapid City, SD, 14 - 30 May 2012.

The specimen test fixture and burner arrangements were assembled IAW UL 94 specifications by an engineer at the CAPE Lab.

Test specimens were prepared and preconditioned IAW UL 94.

Test Narrative

Flammability testing consists of two separate tests, horizontal burning and vertical burning tests. Each test was applied to test samples that had been preconditioned. In the case of horizontal burning, preconditioning consisted of 48 hours storage at room temperature and approximately 50 % humidity. Vertical testing required two separate sets of samples; one set was preconditioned using the same conditions specified for horizontal burning and one set was preconditioned for seven days at approximately 70^{o} C, and 25 % relative humidity. These samples were stored in a desiccator following preconditioning, and removed just prior to the actual testing.

The specific details of the preconditioning and testing requirements may be reviewed in Annex A, the flammability test document, which is attached to this report.

The horizontal burning tests were accomplished first, followed by the vertical burning tests.

Test Results

Horizontal Testing:

A total of eighteen samples were tested, including six samples from the Spring Plate, six samples from the Sport Heel Cradle, and six samples from the Safety Heel Cradle. Each sample was individually marked. IAW UL 94, the samples were tested in groups of three samples.

As specified in UL 94, each specimen was subjected to the burner's flame twice. No sample burned long enough to reach the 25 mm start mark. No samples exhibited any significant burning time with the first application of the flame. Three samples taken from Spring Plates exhibited a short burn time after the second application of flame. The samples that exhibited any burning were all self-extinguishing. Three samples taken from Sport Heel Cradles exhibited a short burn time after the second application of flame. The samples that exhibited any burning were all self-extinguishing. There was no burning exhibited by the Safety Heel Cradles.

The details may be reviewed in the spreadsheet of test results at Annex B. It is noted that while no burns reached or exceeded the 25 mm mark, an exemplar linear burning rate, V, was calculated on the basis of the six samples that displayed any burning at all. UL 94 requires that the burn must reach and exceed the 25 mm mark before the burning length (L) can be measured as valid. Therefore, IAW UL 94 procedures, no horizontal burning samples exhibited any significant burning at all.

All of the samples, for the Spring Plate and for both models of the Heel Cradles are classified as HB.

Vertical Testing:

As specified in UL 94, two separate types of preconditioned test samples were required. Each set of samples was tested separately and IAW UL 94.

Thirty samples, preconditioned for 48 hours, were tested. Ten samples were taken from Spring Plates; ten samples were taken from Sport Heel Cradles; and ten samples were taken from Safety Heel Cradles. IAW UL 94, the samples were tested in groups of five samples. No samples exhibited any measureable t_1 time. Two of the samples from Spring Plates exhibited a measureable t_2 burn time, but were self-extinguishing. Five samples from the Sport Heel Cradle exhibited a measureable t_2 burn time; three of those samples burned to the clamp, and two were self extinguishing. There were no significant t_3 times measured. No samples from any Safety Heel Cradles exhibited any measureable burn times at all.

Thirty samples, preconditioned for 7 days, were tested. Ten samples were taken from Spring Plates; ten samples were taken from Sport Heel Cradles; and ten samples were taken from Safety Heel Cradles. IAW UL 94, the samples were tested in groups of five samples. No samples exhibited a measureable t_1 time. Three samples from the Spring Plates exhibited a measureable t_2 burn time, but were self extinguishing and none burned to the clamp; five of the samples taken from Sport Heel Cradles exhibited a measureable t_2 burn time and four burned to the clamp, all four burned samples were traced back to the same Sport Heel Cradle. There were no significant t_3 times measured. No samples from any Safety Heel Cradles exhibited any measureable burn times at all.

Twenty-six of the samples with no significant burn time, consisting of both the Spring Plate and the two models of the Heel Cradles, may be classified as V-0. The remaining four samples were traced back to the same Sport Heel Cradle. We have no explanation why this one Sport Heel Cradle performed differently from the rest. Our manufacturer, Rocket Composites Inc, has researched their production methods and could find no difference in the processing or in the materials of any of the Sport Heel Cradles. It is further noted that an examination of the burned samples clearly show that what was burned is the epoxy resin used to laminate the carbon fiber composite material, and not the carbon fiber itself. The carbon fiber was delaminated as the epoxy resin was burned off of the samples.

The overall Vertical Burning classification is V-0.

A spreadsheet of the documented results for both the horizontal and the vertical flammability testing may be found at Annex B. Photographs of the test set up and actual test results are at Annex C.

Conclusions

The flammability testing of the Kingetics orthotics has been completed for both the horizontal and the vertical burning efforts.

The horizontal burn tests resulted in a rating of "HB" for the Spring Plate and for both the Safety and Sport Heel Cradles. The vertical burn tests resulted in a rating of "V-0" for the Spring Plate and for both the Safety and Sport Heel Cradles.

Future Testing Requirements

There are no future testing initiatives contemplated during this Phase of the SBIR effort. If follow-on Phases are funded, additional vertical flammability testing may be included. One issue that may be reviewed is the addition of surface coatings to further reduce the flammability, if required.