Evaluations of Protalus Insoles

Protalus Insoles:	M100 T100
Comparison Insoles:	Stock EVA Superfeet

November 1, 2019

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Prepared for
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Contents

Summary

This report summarizes a study of Protalus’ M100 and T100 products (Figure 1). The purpose of these products was to evaluate the insoles’ effects on the alignment of the lower leg and foot, and plantar loads during treadmill walking.

Alignment

- Compared with the reference EVA insole, the M100 reduced total pronation between the tibia and the heel on average of 65% from 9.0° to 3.2° and between tibia and arch by an average of 31% from 5.8° to 4.0°.
- The T100 reduced the deviation from neutral by 45% from 9.2° to 5.0° in the heel and by 56% from 5.8° to 2.6°.

Impact Attenuation (Shock Absorption)

- The Protalus insoles demonstrated superior impact attenuation in both heel (by 20%) and forefoot (by 15%), compared with both the EVA and Superfeet insoles.

Cushioning – Peak Pressure Reduction

- In the heel, the Superfeet and both Protalus insoles reduced peak pressure compared with the EVA control, by an average of 8%.
- In the MTPJ region (the ball of the foot), Superfeet produced significantly higher peak pressures than EVA and the Protalus insoles.
- Superfeet peaks were also significantly higher than either Protalus insoles, by an average of 13%. No statistically significant differences between Protalus M100 and T100 were observed.
- The Superfeet, and both Protalus insoles reduced peak pressure rates compared with the EVA control ($P<0.05$), by an average of 16%. The small differences between Superfeet and Protalus insoles were (~6%) were not significantly different at the required level of probability.
- No statistically significant differences between Protalus M100 and T100 were observed.

Subjective Ratings

- Overall, subjects gave statistically higher ratings to the Protalus insoles than to the EVA control for “comfort”, “stability” and support”.
- Both Protalus insoles were also rated more comfortable than the Superfeet comparator, consistent with the observed reductions in pressure loads on the sole of the foot.

Introduction

Insoles are commonly employed in shoes to enhance comfort, support the arch or the foot or to correct for foot alignment problems. Unlike orthotic inserts, which are generally prescribed by a podiatrist, orthotist or physical therapist, insoles are widely available, over the counter, in shoe stores, pharmacies, supermarkets and other retail outlets, and online.

This report concerns various prototype and production insoles produced by Protalus. Protalus makes certain claims about the effects of their insole designs on the alignment and motion of the lower extremity. Specifically, they believe the insoles result in "a more neutral alignment of the foot", "enhanced pronation control" and "improved cushioning".

In testing the validity of Protalus' claims, we made the following assumptions:

1. Any hypothetical performance enhancements are relative to a basic insole of the type commonly supplied with an athletic or casual shoe – typically consisting of a single layer of single density EVA foam some 3-5 mm thick, sometimes with an additional textile covering.
2. Comparison of the Protalus product with a "standard" EVA insole is appropriate for the purposes of testing the claims.
3. "Alignment" and "pronation" refer to the ankle and foot and have the meanings commonly used in the footwear and foot health communities.
4. "Improved cushioning" implies one or more of the following: (1) increase in *in-vitro* impact attenuation compared with the control shoe (2) decrease in the peak pressure loads on the plantar surface of the foot (2) decrease in the peak rates of plantar pressure loading.
5. That a claim is "valid" if the measured difference between Protalus and control insoles exceeds the commonly accepted level required for statistical significance ($p<0.05$).

The definitions implicit in these assumptions allowed us to design a series of tests and measurements to objectively test the validity of Protalus' claims.

Disclosure

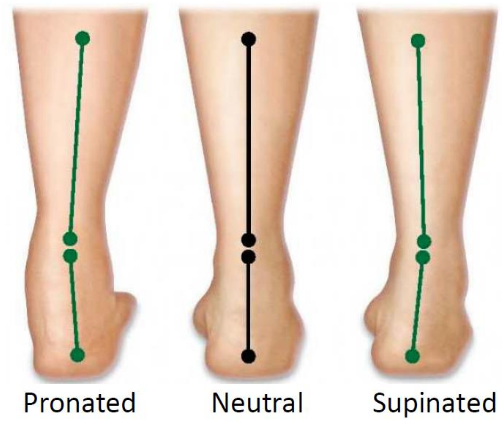
- BioMechanica, LLC is a privately owned, independent company that provides biomechanics research, testing and other technical services to the sporting goods, military and medical industries.
- Protalus established the general purpose of the studies reported here (i.e. "Test the validity of our claims") and selected the insole conditions to be compared. BioMechanica had sole responsibility for selection of the tests and measurement methodologies employed, the execution of the experiments and tests, data reduction, statistical analysis and preparation of this report(s). We also added a basic EVA insole to the study as an additional control comparison.
- The studies described in this report were performed as "work for hire" subject to our usual terms of business. Compensation for this work was predetermined and not dependent on the studies' outcomes.
- BioMechanica LLC and its employees, partners and associates do not endorse products or services and do not allow their clients to use their names, images or work product in any context that suggests endorsement or approval of a product or service.

Background

Alignment and Pronation

The “pronation paradigm” has been a dominant theme in podiatry, orthotic treatment and athletic footwear design for many years. The paradigm is based on the notion that excessive pronation of the foot is a significant factor in a number of common foot and lower leg injuries.

Commonly, pronation is depicted as shown at right, in a posterior or “rearfoot” view. From this perspective, “pronation” is a rolling inward of foot ankle and “supination” is a rolling motion in the opposite direction.



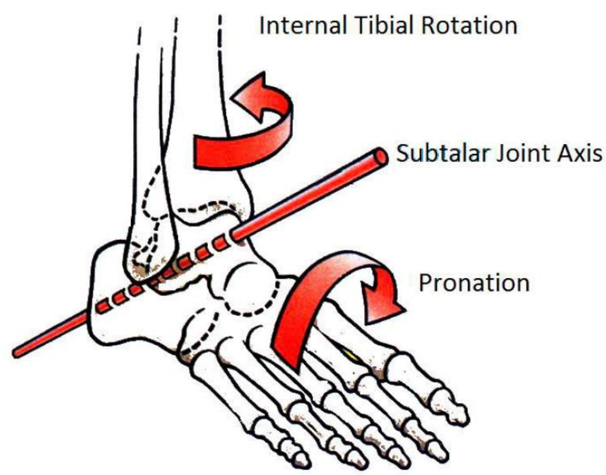
Right Foot

Pronation-supination is more complicated than the 2D rearfoot view suggests. It is a motion about the talo-calcaneal (“subtalar”) joint that combines “rolling” of the heel with external rotation (“turning out”) of the foot and dorsiflexion (“toes up” flexion).

Also, since the talus also connects to the midfoot, most importantly to the navicular bone, pronation also involves motion of the midfoot and arch.

The complex 3D motion occurs because the ankle is not a simple hinge joint, but a combination of joints with different orientations. The subtalar joint axis is tilted, relative to the body’s axes, in all three planes. The “oblique hinge” of the subtalar joint has some important effects:

- The pronation/supination axis is not aligned with any of the major foot and leg axes.
- Pronation is accompanied by a medial shift of the ankle and midfoot (“navicular shift”)
- In a fixed coordinate system, pronation of the foot requires compensatory internal rotation of the tibia.



Pronation and Injury

"Excessive" pronation and lower extremity misalignment are considered risk factors for musculoskeletal pain and injury, including knee and back pain, Achilles tendinitis, plantar fasciitis and other common injuries. Very briefly, the pronation paradigm purports the following:

1. Flat, flexible feet pronate excessively, resulting in abnormal loading of the foot and transmission of twisting forces to the knee. Such feet require correction in the form of arch support, medial posting, etc. to resist pronation.
2. High arched feet are rigid and do not pronate enough. Pronation and flexion of the arch are themselves internal cushioning mechanisms that absorb loads on the foot. Such feet are inherently stable but require cushioning to compensate for the lack of foot flexibility.
3. Ideally, the foot should be "neutrally" aligned, i.e. neither pronated nor supinated.

It is important to note that views on the value of the pronation paradigm vary and that some elements of it have not been supported by controlled laboratory studies – particularly regarding the effectiveness of so-called "stability" running shoes on pronation and lower extremity injury rates. However, podiatrists, physical therapists and sports medicine specialists, who use *prescription orthotics and insoles* rather than shoe modifications, continue to report effective interventions using the "pronation" and "pronation control" paradigms for diagnosis and treatment of lower extremity injuries.

Cushioning

"Cushioning" in footwear has three functions:

1. *Reduction of local peak pressure (stress) on the plantar surface of the foot.*
   Excessive repetitive stresses are implicated in various pathologies from minor discomfort and bruising to stress fractures.
2. *Reduction of loading rate*:
   Higher loading rates at the plantar surface are indicative of "impact". Whereas the effects of cushioning on peak pressures are generally limited to the foot itself, variations in impact loading are transmitted through the musculo-skeletal system. The repetitive stresses produced during walking and running can have cumulative effects, resulting in "overuse" injuries. Since bone and soft tissues are more susceptible to loads applied at high frequencies, lower loading rates are desirable.
3. *Enhancement of the perception of comfort*:
   "Comfort" is a psychological outcome, not a physical property of an insole or cushioning system. Cushioning systems that reduce pressure and impact stresses tend to be perceived as "more comfortable". However, in footwear, load-related comfort perception may be confounded with other factors including fit, flexibility and ventilation.

Insole Conditions

Samples of three insole models from regular production and retail sources were provided by the client. For each insole, the specimens made available included multiple pairs of whole sizes in US Women's size 8 – 10 and US Men's 9 – 12.

The four models consisted of two Protalus insoles (M100 and T100), and an after-market insole (Superfeet). We added an additional control condition, the EVA insole supplied with the reference shoes (Figure 1).

EVA

(Control)

Superfeet "Green"

(Comparator)

Protalus M100

Protalus T100

Figure 1: Insole Conditions

Insole Physical Characteristics

Weight was measured using an electronic laboratory scale to the nearest gram.

Heel and forefoot thicknesses were measured at the locations specified by ASTM F1976[1] using a Keyence GT2 H50 digital sensor and recorded to the nearest 0.1 mm.

The measurements reported below are for US Men's size 11 insoles

Condition	Weight*		Thickness, mm	
	gm	oz	Heel	Forefoot
EVA	10	0.4	5.0	4.0
Superfeet	50	1.8	8.0	5.0
Protalus M100	57	2.0	10.4	6.5
Protalus T100	52	1.8	8.4	5.3

** per insole*

Reference Shoes

Insoles were tested in conjunction with a "generic" running shoe model having a single density EVA sole and a synthetic mesh upper. Shoes were made available in multiple sizes from US Women' 7 to US Men's 12.

[1] ASTM F1976 - 13 Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials; ASTM International, West Conshohocken PA USA; www.astm,org

Methods and Test Protocols

Human Subjects

We examined the effects of insoles on lower extremity alignment and plantar surface loads in human subjects. Alignment measurements were made during quiet standing and pressure distributions measured during walking on a treadmill at a self-selected “comfortable” pace.

Subjects

Thirty-nine subjects (30 male, 9 female) were recruited from our pool. The available subject pool includes subjects recruited via local running and walking shoe stores, running clubs and exercise groups.

Eligibility Criteria

Participating subjects were required to meet the following criteria:

- Healthy active adult, 18 years or older (15-18 with parental consent).
- Shoe size within the range of available product.
- Regular participant in exercise walking or running
- No recent or chronic musculoskeletal injuries or pain.
- No foot infections (e.g. athlete’s foot, plantar warts, toe fungus, etc.)
- Familiar with walking on a treadmill, or willing to spend an additional 20 - 30 minutes on treadmill familiarization.

Informed Consent and Waiver of Liability; Subject Profile

Prior to any data collection, all subjects read and signed an “Informed Consent and Waiver of Liability” agreement document explaining the purpose of the experiment, what was required of participants and describing the potential risk and hazards involved. For minor subjects that had not reached their 18th birthday, parental consent was also given.

Compensation

Once they had agreed to participate, subjects were offered a cash honorarium of US $25. Subjects were not required to complete the experiment, or meet any other requirements, in order to be compensated.

Subject Characteristics

Average subject characteristics are described in the table below. individual subject data on the next page. Individual subject data are reported in Appendix 3.

	Age	Mass	Stature	BMI	Walking Speed	
	y	kg	cm	kg m^{-2}	mph	m s^{-1}
Mean	38	79.2	177	25.2	2.1	0.95
sd	15	16.0	7	4.6	0.4	0.19
Min	17	50.0	165	17.3	1.2	0.54
Max	69	116.4	191	37.3	3.0	1.34

Treadmill Walking Protocols

After *ad libitum* warm-up, marker attachment and sensor setup, subjects walked on a motorized treadmill at a self-selected “brisk” walking speed wearing a generic, “neutral-cushioned” running shoe of appropriate size for 2-3 minutes. Experimental conditions were presented in balanced order using a Latin Squares method. Two trials were performed in each of the experimental conditions – one for motion capture and the second for pressure distribution measurements. During the last minute of each trial, data were collected for 30 - 60 seconds.

Data Collection

Natural Point’s “Tracking Tools” software was used to calibrate the motion capture system and to track the motion of markers in three dimensions.

Calibration was performed using the Tracking Tools 3-marker wand protocol at the “Very High” quality level and a 3-point ground plane reference to define the coordinate system. The high camera number, close-range camera locations and standard pixel-averaging methods resulted in sub-millimeter tracking precision, typically in the range 0.2 - 0.5 mm.

Marker triads were defined as rigid bodies in Tracking Tools so the software reported triads positions and orientations in addition to individual marker trajectories. For computational efficiency, rigid body orientations were recorded as quaternions.

Data Analysis

Rigid body trajectories were low-pass filtered using a 4^{th} order, zero-lag Butterworth digital filter with a 3dB cutoff frequency of 25 Hz. Relative orientations of body segments (3D joint angles) were computed using quaternion calculus.

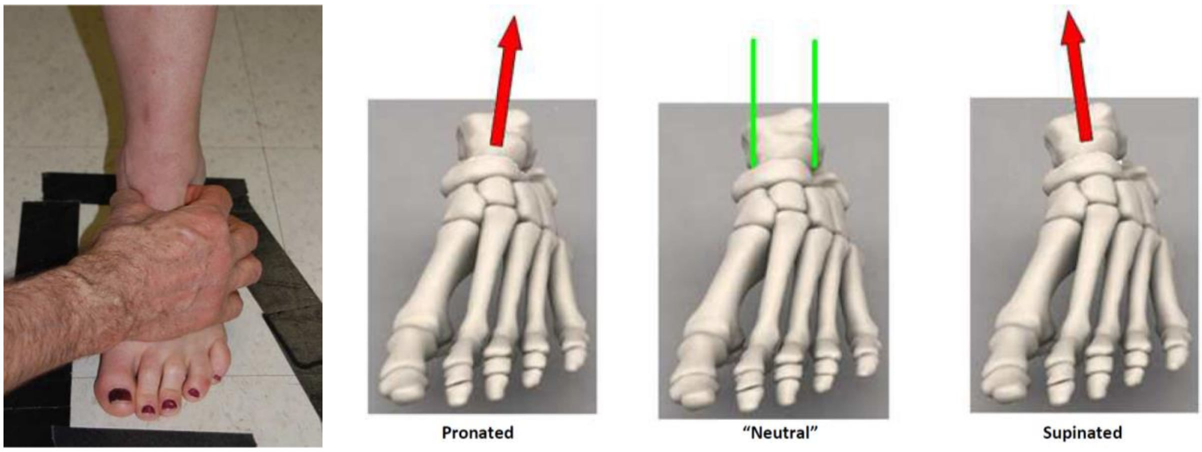
Pronation of the arch and heel were calculated as the combination of eversion and adduction, assuming all dorsiflexion was attributed to the ankle joint. Internal tibia rotation was calculated as internal rotation about the long axis of the tibia, relative to foot.

Lower Extremity Alignment

Alignment and Subtalar Neutral

Baseline measurements of lower extremity alignment were made barefoot and in each shoe insole conditions in each case (a) with the subject in relaxed stance and (b) with the subtalar joint aligned in an anatomically “neutral” orientation.

The subtalar neutral position acts as a “zero” reference alignment while the relaxed stance position shows the static alignment of the foot and tibial components.



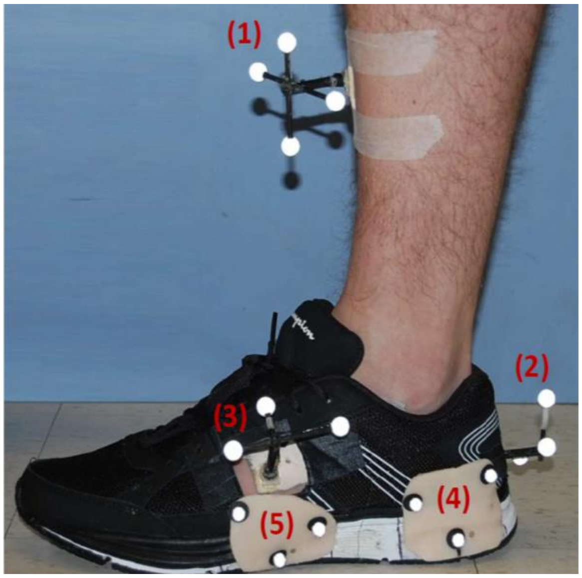
Palpation of Subtalar Neutral

Alignment - Lower Extremity Motion Capture

Lower extremity motion was recorded in three dimensions using a NaturalPoint Optitrack motion capture system with 20 cameras transmitting data at 100 frames per second. Reflective marker triads mounted on lightweight, stiff antennae were used to define body segments as rigid bodies and track the motion of the lower leg, foot and shoe. Antennae were attached to mounting pads of 2 mm thick moldable polymer material. Each pad was custom molded to individual subjects’ anatomy and attached with surgical cement (“skin glue”), supplemented with athletic tape as required. Additional markers on the knee, ankle and foot were used as references to align marker triads with anatomical landmarks but removed after capture of barefoot reference data.

Anterior Posterior Lateral Medial

Example lower extremity marker sets, including reference markers for alignment.



Additional marker triads were used to define the heel and midfoot of the shoe as rigid body segments.

The image at left shows lower leg, foot and shoe marker sets as employed during walking data acquisition with triads defining rigid bodies for the tibia (1), heel (2) and midfoot (3) of the foot and the heel (4) and midfoot (5) of the shoe.

Note that the foot antennae emerge through holes in the shoe, enabling in-shoe motion of the foot to be observed.

Alignment – Data Analysis

Rigid body trajectories were low-pass filtered using a 4th order, zero-lag Butterworth digital filter with a 3dB cutoff frequency of 25 Hz. Relative orientations of body segments (3D joint angles) were computed using quaternion calculus.

Pronation of the arch and heel were calculated as the combination of eversion and adduction, assuming all dorsiflexion was attributed to the ankle joint. Internal tibia rotation was calculated as internal rotation about the long axis of the tibia, relative to foot.

Impact Attenuation - Test Protocol *See Appendix 1 for more details*

The impact test device uses a computer-controlled actuator to lift and drop a missile of specific mass and geometry onto the cushioning system. The impact energy is controlled at 5 Joules, similar to the impact energy typically imparted to a running shoe sole. A load cell and a displacement transducer are used to record the force of impact and the compression of the cushioning system 20000 times per second. Each sample is impacted 30 times. The first 25 drops are used to condition the sample and test scores are determined by averaging results from the five impacts.

Insoles were tested in both the heel and forefoot. The standard test locations (impact centered at 12% and 75% of foot length respectively) coincide with the average locations of peak pressure loads on the foot during walking and running.

Plantar Pressure Distribution

Methods

In-shoe pressure distributions between the insole and the plantar surface of the foot were measured using F-Scan[2] pressure sensing insoles (Figure 3). An insole has between 600 and 1200 individual pressure transducers (depending on size), each representing a 5 mm x 5 mm area. All available transducers in both insoles were sampled synchronously 100 times per second for a period of 30s.

Sensors were calibrated using the manufacturer's recommended procedure.

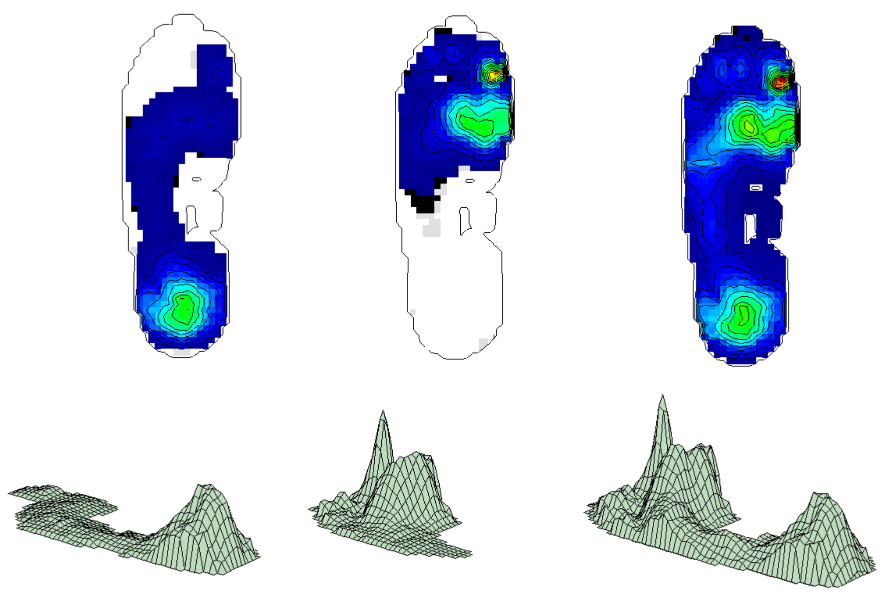
F-Scan in-shoe pressure sensors

Pressure Data Processing

Raw pressure data were spatially smoothed using a 3 x Gaussian filter. Kin the time domain, a 4th order, zero lag, low-pass Butterworth digital filter with a 3 dB cut-off f 25 Hz was applied.

Individual steps were identified and peak regional pressures in the heel and forefoot recorded for each step. The mean of the peak values for all available steps was used to characterize heel and forefoot pressure loads. After finite-difference differentiation of the pressure-time data for each sensing element, characteristic values were similarly calculated for peak loading rate.

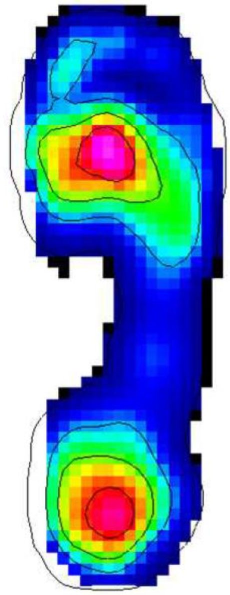
Examples



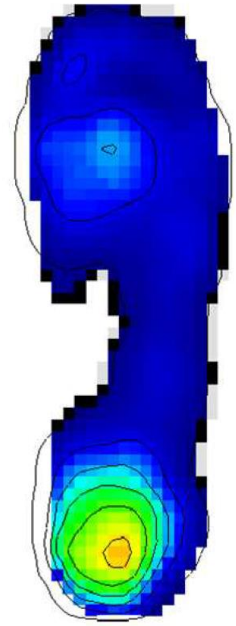
Example pressure distribution at (a) peak heel load (b) peak forefoot load. Intra-step peaks are shown in (c).

[2] https://www.tekscan.com/products-solutions/systems/f-scan-system

- Load distribution on the plantar surface of the foot is primarily determined by the anatomy of the foot.
- As the examples in the figures below show, peak loads typically occur under the bony prominences of the heel, metatarsal heads and big toe; sometimes under lesser toes. High frequency impact loads are similarly borne by bony prominences. During normal walking, significant impact events usually occur only under the heel.
- Both the “hardness” and the curvature of the interface between the foot and the shoe can affect the distribution of loads. “Softer” surfaces and more conforming geometry spread loads over a larger area and reduce peak pressures[3].



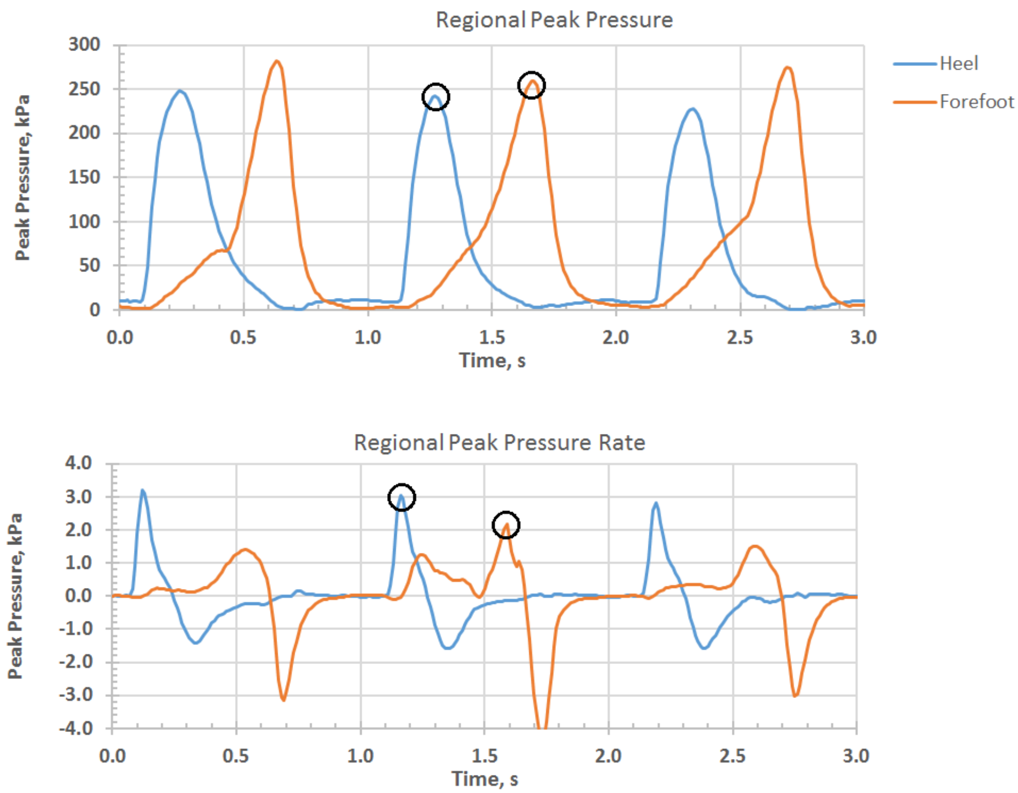
Example mean peak pressure distribution



Example mean peak pressure rate distribution

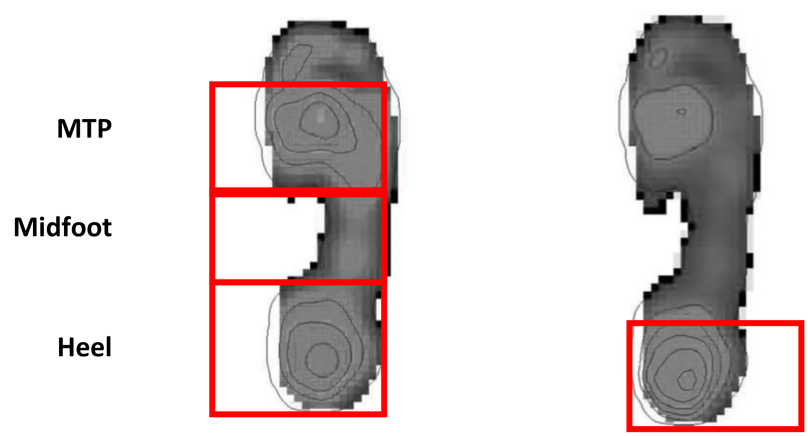
[3] Mientjes, M. & Shorten, M.R. (2011) Contoured cushioning: effects of surface compressibility and curvature on heel pressure distribution. Footwear Science 3(1) : 23:32.

Regional Peaks



Example intra-step regional peak pressure (top) and peak pressure rates for heel and forefoot regions; as a function of time. Example heel and forefoot peak values are circled.

Regional peak pressures were evaluated using "masks" to distinguish three regions of the plantar surface – heel, midfoot and MTP (metatarsal-phalangeal joint region)



Peak Pressure　　Peak Pressure Rate

Results

Static Alignment

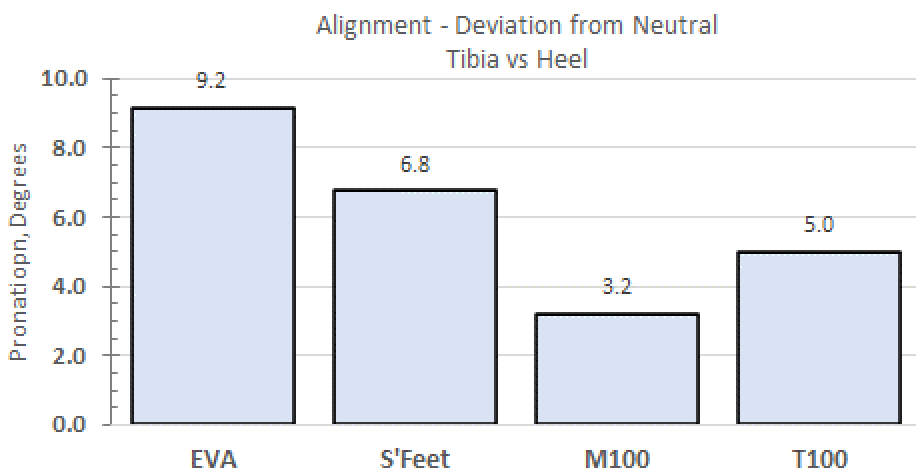
Static alignment data for both the rearfoot (heel) and arch was collected on all four conditions in 31 subjects. Compared with the reference EVA insole, the M100 reduced total pronation between the tibia and the heel on average from 9.0° to 3.2° (65%) and between tibia and arch from 5.8° to 4.0° (31%).

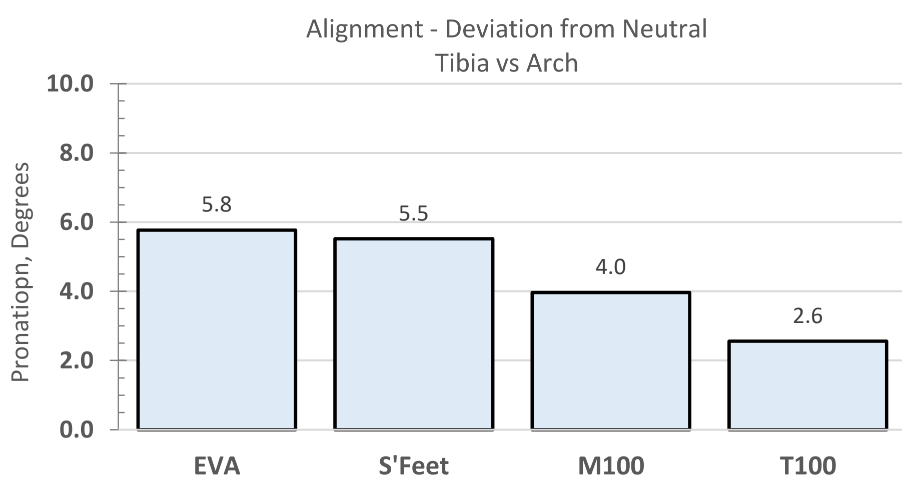
The T100 reduced the deviation from neutral from 9.2° to 5.0° (45%) (heel) and from 5.8° to 2.6° (56%) (arch).

Differences among conditions were statistically significant ($p << 0.005$) except Tibia vs Arch between EVA and Superfeet.

Mean Values – Total Pronation, Deviation from Neutral

Condition		n	Mean		SD Among Subj	
			Tib-HL	Tib-Arch	Tib-HL	Tib-Arch
1	EVA	31	9.2	5.8	4.1	3.3
2	S'Feet	31	6.8	5.5	3.1	3.3
3	M100	31	3.2	4.0	1.5	2.1
4	T100	31	5.0	2.6	1.8	1.0





Impact Attenuation

See also Appendix 2

Impact attenuation was determined by comparing peak impact shock scores from each insole with the reference condition (no insole) and expressing the reduction in impact shock as a percentage.

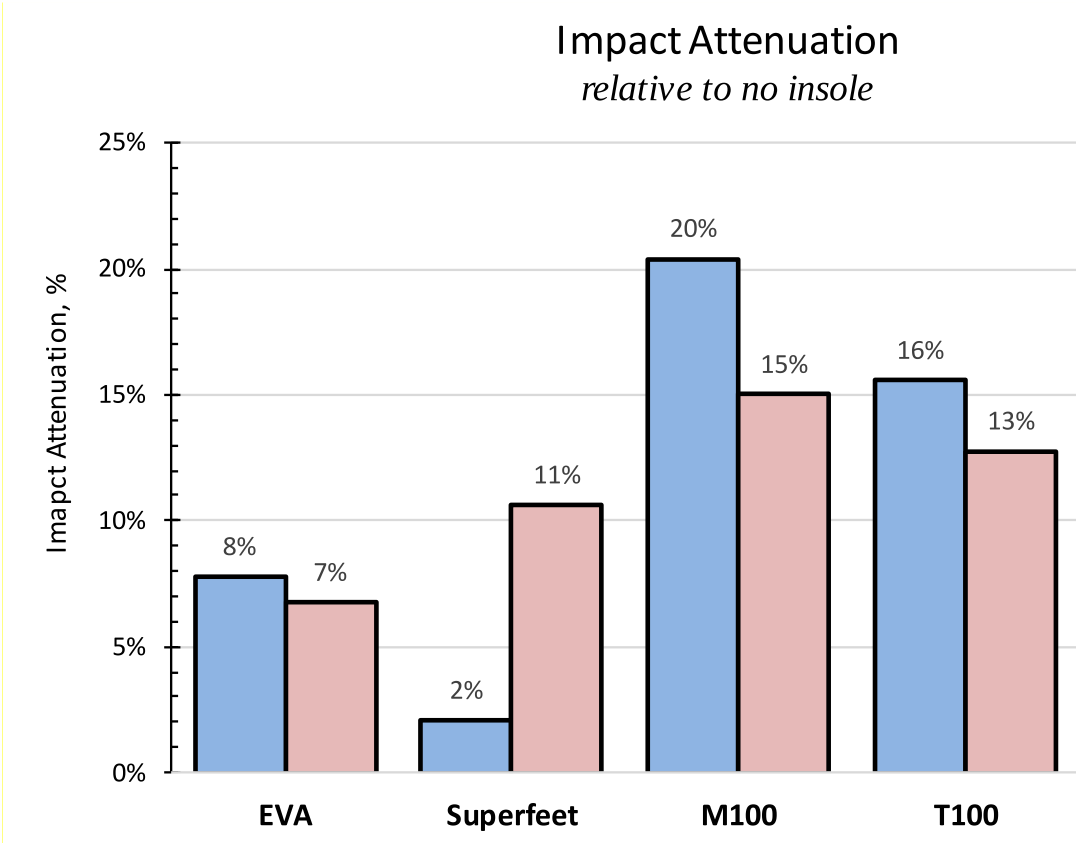
Test Results: Description and Interpretation

Measurement	Symbol	Units	Description
Energy Input	Ein	J	The total energy input into the specimen during the impact, equivalent to the potential and kinetic energy of the impactor at first contact. The required energy input for a test is pre-determined and controlled by the system.
Thickness	Thk	mm	Total thickness of the test specimen; i.e. base sole _ insole.
Energy Input	Ein	J	Total energy input to the cushioning system by the impact; typically standardized at 5 Joules.
Peak Impact Shock	g-max	g	The peak value of acceleration recorded during the impact, expressed in gravitational ("g") units. *Lower* values indicate greater impact attenuation.
Peak Displacement	x-max	mm	The maximum compressive displacement of the specimen during an impact. Greater values indicate more compliant cushioning.
Energy Return	Eret	%	The percentage of the input energy that is recovered during rebound. High values indicate a more "springy" material. Lower values indicate a more "energy absorbent" or "conforming" cushioning material.
Impact Attenuation	A	%	The ratio of the g-max score to that produced by a reference cushioning system. Higher values indicate more impact attenuation.

Impact Test Results

See Appendix 2 for more details

	Test #	Insole	Ein	g-max	x-maxj	Eret	A
			J	g	mm	%	%
Heel	9608	No insole	5.0	13.0	9.7	54.8	0%
	9610	EVA	5.0	12.0	12.0	56.4	8%
	9612	Superfeet	5.0	12.7	12.6	54.7	2%
	9614	M100	5.0	10.3	14.8	55.0	20%
	9616	T100	5.0	11.0	14.7	55.8	16%
Forefoot	9609	No insole	5.0	16.9	9.9	56.7	0%
	9611	EVA	5.0	15.8	11.7	57.1	7%
	9613	Superfeet	5.0	15.1	11.7	52.3	11%
	9615	M100	5.0	14.4	11.5	52.4	15%
	9617	T100	5.0	14.8	12.1	53.3	13%



Impact Attenuation
relative to no insole
Imapct Attenuation, %
25%
20%
15%
10%
5%
0%
8%
7%
2%
11%
20%
15%
16%
13%
EVA
Superfeet
M100
T100

Plantar Pressure Distribution

Peak Pressure

See also Appendix 4

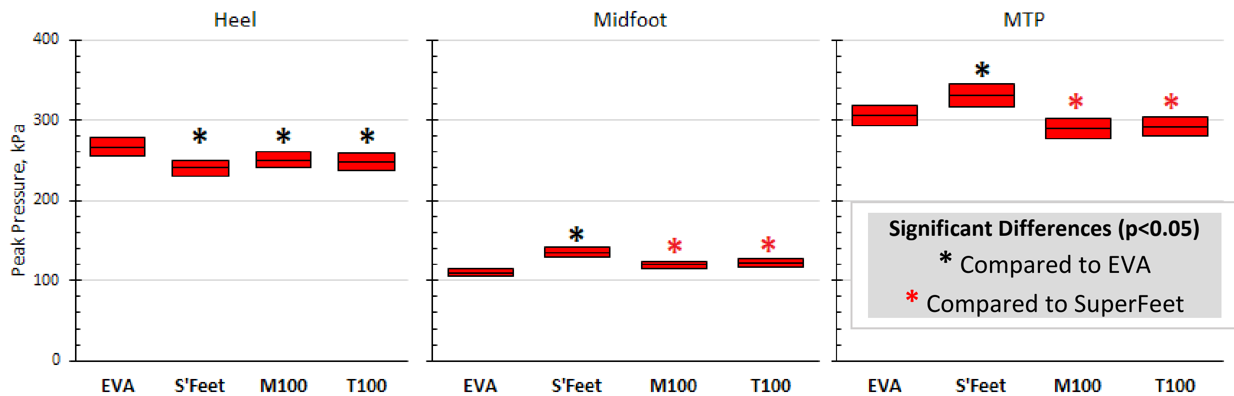
Peak Pressure (kPa)
by region, means of left and right feet.

	Heel				Midfoot				MTP			
	C1	C2	C3	C4	C1	C2	C3	C4	C1	C2	C3	C4
	EVA	S'Feet	M100	T100	EVA	S'Feet	M100	T100	EVA	S'Feet	M100	T100
Mean	278	249	261	258	117	142	125	130	315	349	301	304
sd_1	74	70	70	69	52	70	73	65	127	149	103	103
sd_2	11	10	10	10	5	6	5	5	13	14	12	12

Standard deviations:

sd_1	Standard deviation **among** subjects – an indicator of the variability of results across subjects;
sd_2	Standard deviation **within** subjects – an indicator of the variability of results from step to step in an individual trial

Peak Pressure ± sd_1



Statistical Comparisons

For each result repeated measures Analysis of Variance (ANOVA) was used to compare differences among mean values for each condition. In each case, significant differences were observed (p<0.05). Post-hoc comparisons using t-tests were used to test for differences among individual means.

- In the heel, the Superfeet, and both Protalus insoles reduced peak pressure compared with the EVA control, by an average of 8%.
- In the midfoot, Superfeet and both Protalus insoles, produced significantly higher peak pressures than EVA. Superfeet peaks were also significantly higher than either Protalus insoles. Higher pressures in the non-EVA insoles an expected result of the arch support function of these products.
- In the MTP region, Superfeet, produced significantly higher peak pressures than EVA and the Protalus insoles. Superfeet peaks were also significantly higher than either Protalus insoles, by an average of 13%.
- No statistically significant differences between Protalus M100 and T100 were observed.

Peak Pressure Loading Rate

See also Appendix 5

Peak Pressure Rate (MPa s^{-1})
by region, means of left and right feet.

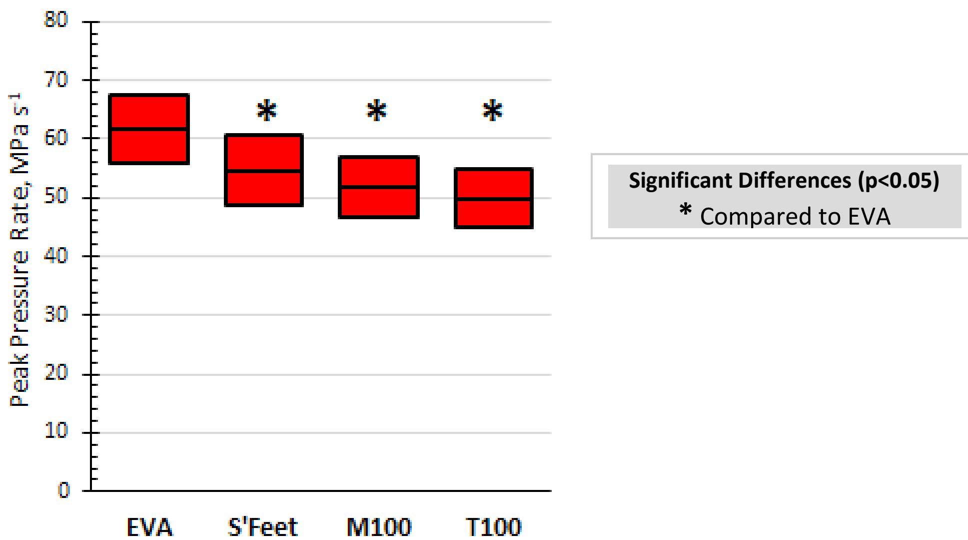
	Heel			
	C1	C2	C3	C4
	EVA	**S'Feet**	**M100**	**T100**
Mean	62	55	52	50
sd_1	18	17	19	14
sd_2	6	6	5	5

Standard Deviations

sd_1 Standard deviation **among** subjects – an indicator of the variability of results across subjects;

sd_2 Standard deviation **within** subjects – an indicator of the variability of results from step to step in an individual trial.

Peak Pressure Rate ± sd_1



Statistical Comparisons

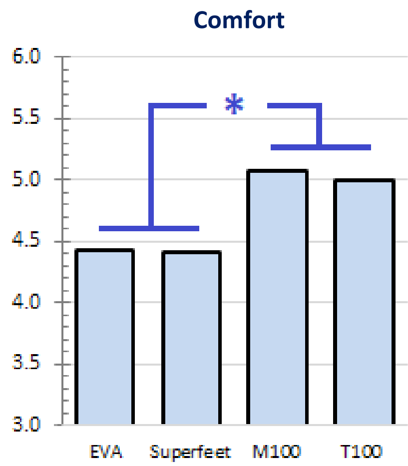
repeated measures Analysis of Variance (ANOVA) was used to compare differences among mean values of heel peak pressure rate for each condition. Significant differences were observed ($p<0.05$). Post-hoc comparisons using *t*-tests were used to test for differences among individual means.

- The Superfeet, and both Protalus insoles reduced peak pressure rates compared with the EVA control (P<0.05), by an average of 16%.
- The small differences between Superfeet and Protalus insoles were (~6%) were not significantly different at the required level of probability.
- No statistically significant differences between Protalus M100 and T100 were observed.

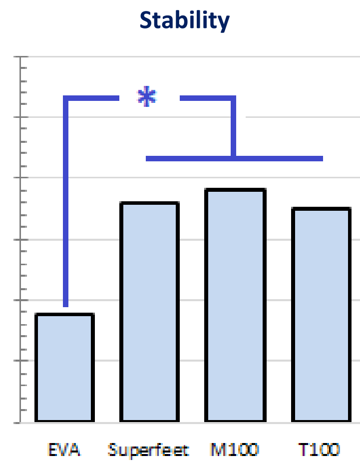
Subjective Ratings

See also Appendix 6

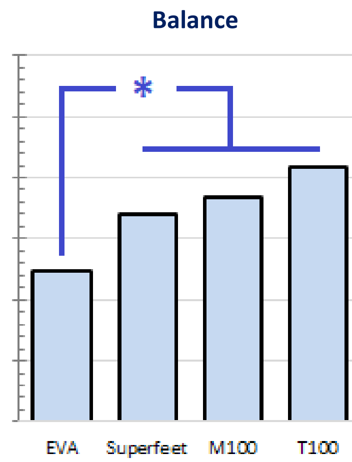
Subjects were asked to provide their ratings of “Comfort” Support” and “Balance” on a 1-7 scale. In the charts below, the bars show mean values. An asterisk (*) indicates a statistically difference among conditions or groups of conditions ($p<0.05$). Detailed data are reported in Appendix 6.



The two Protalus insoles had the highest average cushioning ratings. Ratings for both the Protalus M100 and T100 insoles were statistically significantly higher than the EVA and Superfeet models.



The experimental conditions were all rated significantly higher than the EVA control.



The experimental conditions were all rated significantly higher than the EVA control.

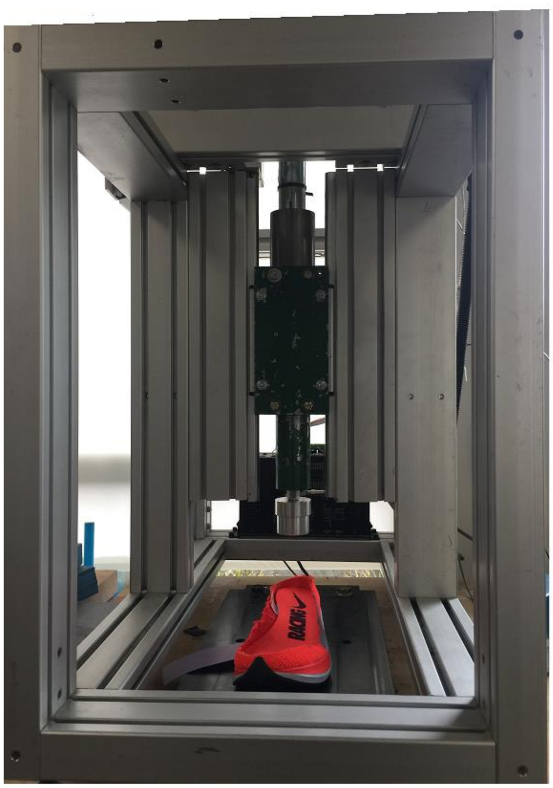
Appendix 1: Impact Test Method

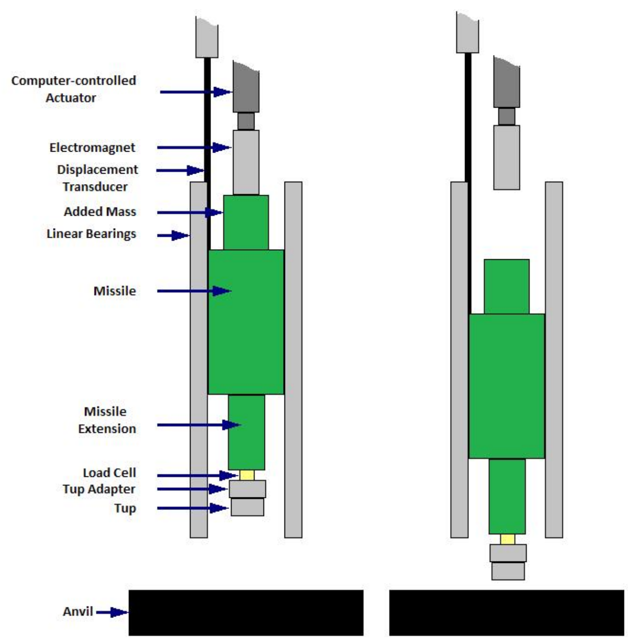
ASTM Standard Method

Heel and forefoot Impact tests were performed on each specimen in accordance with ASTM F1976-13 *Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials*[4]. This method is also recognized by the American National Standards Institute (ANSI) as an American National Standard.

Summary of the Method

The impact test device uses a computer controlled actuator to lift and drop a missile of specific mass and geometry onto the cushioning system. The impact energy is controlled at 5 Joules, similar to the impact energy typically imparted to a running shoe sole. A load cell and a displacement transducer are used to record the force of impact and the compression of the cushioning system 20000 times per second. Each sample is impacted 30 times. The first 25 drops are used to condition the sample and test scores are determined by averaging results from the five impacts.





4 ASTM International, West Conshoken, PA. https://www.astm.org/Standards/F1976.htm

Specifications

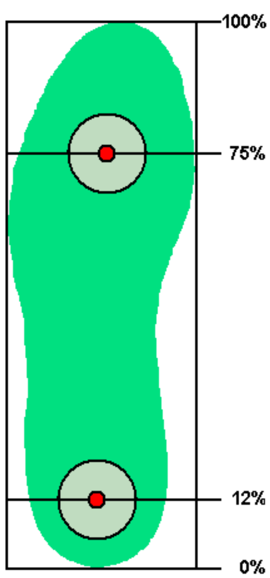
The standard includes the following specifications:

Impactor mass	8.5	kg
Tup face diameter	45	mm
Tup face bevel radius	1	mm
Conditioning drops	25	
Measurement drops	5	s
Measurement interval	2	s

- Tests were performed at room temperature (70 ± 2°F) after materials had conditioned to the laboratory environment for more than 24 h.
- A total impact energy of 5.0 J was applied in both heel and the forefoot.

The compete standard is available online[1].

Test Locations

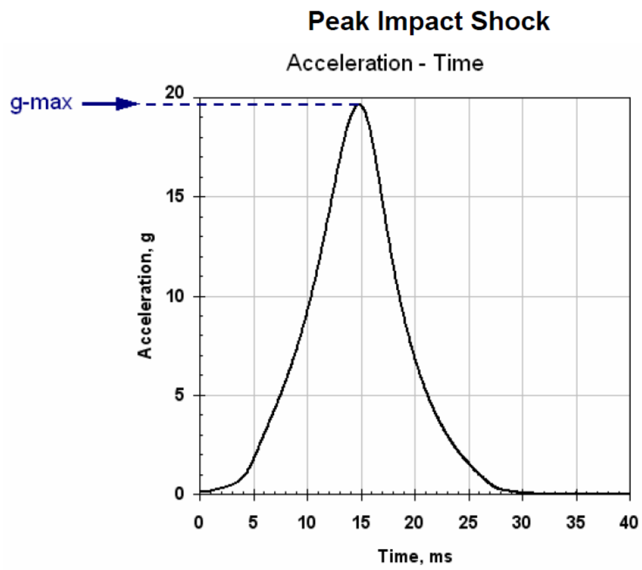


ASTM F1976 specifies that impact tests be centered at specific locations on the shoe sole. These are at 12% (heel) and 75% (forefoot) of foot (insole) length from the heel respectively, along the midline. These points coincide with the average locations of peak pressure loads during running.

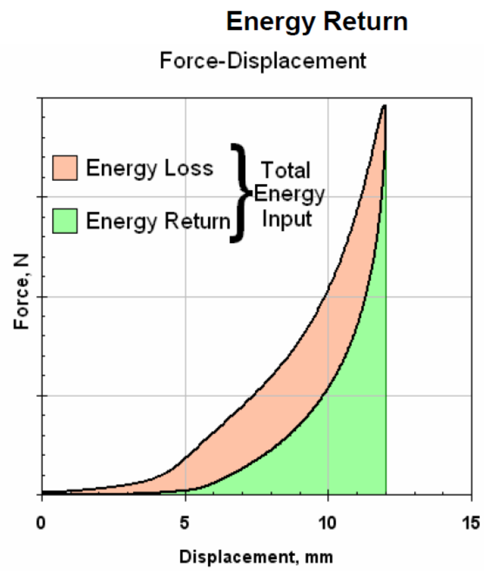
To promote repeatable identification of measurement locations, we use templates shaped to the bottom net of typical lasts, with holes drilled at the specified points, to mark the soles.

Marks placed using the templates identify the locations of both thickness measurements and impact tests.

Impact Test Outcomes and their Interpretation

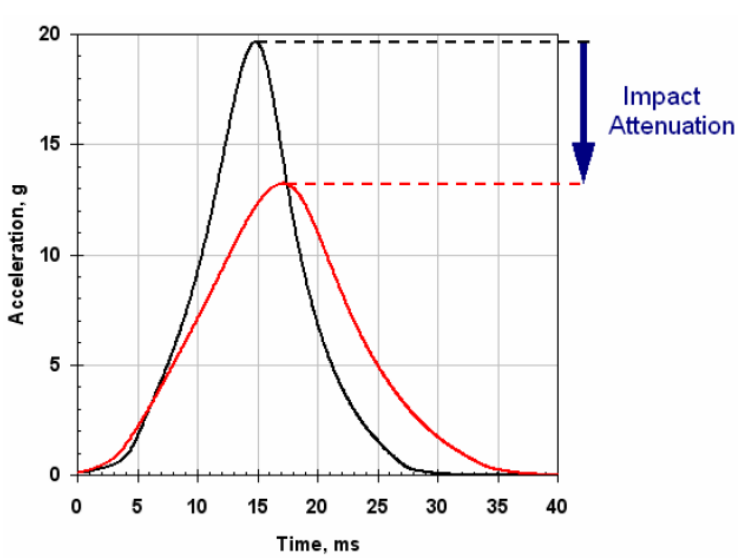


The impact acceleration-time curve shows a characteristic peak. The value of this peak is the peak impact shock (g-max) score



The area under the ascending portion of the force-displacement curve is the total impact energy input into the cushioning system. The area inside the hysteresis loop (red shading) is the energy loss. ("Lost" energy is dissipated as heat.) the remaining energy (green shading) is the energy of the rebound ("Energy Return")

Impact Attenuation



When two cushioning systems are compared, the impact attenuation can be determined as the relative reduction in peak impact shock. In this study, impact attenuation scores were calculated relative to the peak impact shock produced running shoe sole with "typical" cushioning properties.

Impact Test Measures

Measurement	Symbol	Units	Description[5]
Energy Input	Ein	J	The total energy input into the specimen during the impact, equivalent to the potential and kinetic energy of the impactor at first contact. The required energy input for a test is pre-determined and controlled by the system.
Peak Impact Shock	g-max	g	The peak value of acceleration recorded during the impact, expressed in gravitational ("g") units. *Lower* values indicate greater impact attenuation.
Peak Displacement	x-max	mm	The maximum compressive displacement of the specimen during an impact. Greater values indicate more compliant cushioning.
Impact Attenuation	A		The ratio of the g-max score to that produced by a reference cushioning system
Energy Return	Eret	%	The percentage of the input energy that is recovered during rebound. High values indicate a more "springy" material. Lower values indicate a more "energy absorbent" or "conforming" cushioning material.

Repeatability and Precision

Contemporaneously with the shoe sole tests, additional series of tests were performed to document the repeatability and precision of the test method. These tests were performed on two modular elastomer programmers (MEPs) An MEP is pad of material, typically made of flexible polyurethane that has generally linear elastic properties and is highly durable. Such pads are typically used as a consistent impact target for calibration and systems checking of impact testers.

Based on the results of these tests, the repeatability and precision of the test method were determined as follows:

	Parameter			
	Ein	g-max	x-max	Eret
	J	g	mm	%
Mean Value	4.99	14.00	8.48	54.37
Repeatability standard deviation	0.020	0.058	0.095	0.179
Coefficient of variation (%)	0.4%	0.4%	1.1%	0.3%
95% Precision Interval	0.04	0.16	0.34	0.46
99% Precision Interval	0.06	0.21	0.45	0.62
95% Precision Interval (% mean)	0.9%	1.1%	4.0%	0.9%
99% Precision Interval (% mean)	1.2%	5%	5.3%	1.1%

[5] These descriptions are the authors' and not part of the ASTM standard.

Appendix 2: Impact Attenuation Results

BioMechanica

Footwear Impact Test Results

Client:	Protalus	Test Date:	
Attn:	Chris Buck	Report Date:	
Project	Protalus Insole Comparisons	Authors:	MS / EP

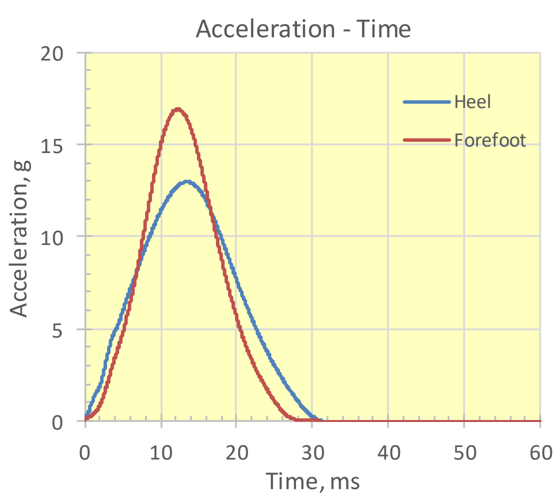
Method: ASTM F1976-13 Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials
https://www.astm.org/Standards/F1976.htm

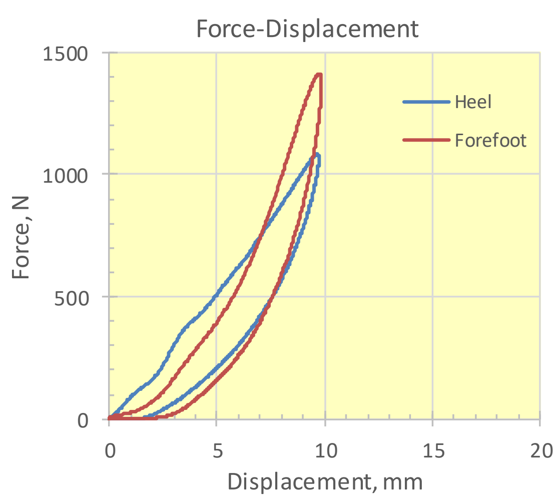
Specimen: Base - No Insole

Thickness HL: 27.0 mm
FF: 18.5 mm

Results:

		Test #	Ein	g-max	x-max	t-max	Eret	k	CE	n
			J	g	mm	ms	%	kN/m		
Heel	Mean	9608	4.99	13.0	9.7	13.5	54.8	105.8	0.171	1.11
	sd		0.01	0.0	0.0	0.0	0.0	0.3	0.000	0.00
Forefoot	Mean	9609	4.99	16.9	9.9	12.3	56.7	182.1	0.192	1.79
	sd		0.01	0.0	0.1	0.1	0.2	0.9	0.000	0.02





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Footwear Impact Test Results

Client:	Protalus	Test Date:	
Attn:	Chris Buck	Report Date:	
Project	Protalus Insole Comparisons	Authors:	MS / EP

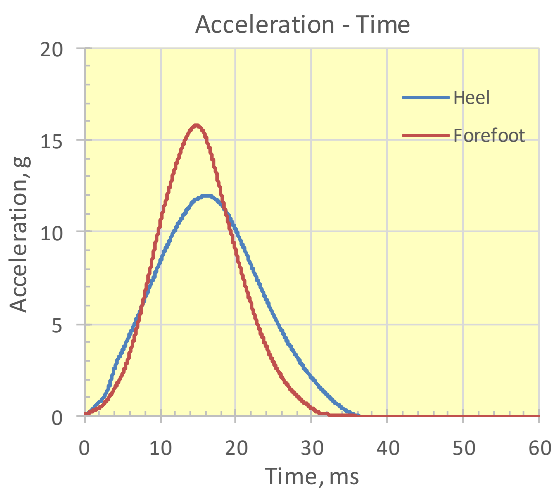
Method: ASTM F1976-13 Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials
https://www.astm.org/Standards/F1976.htm

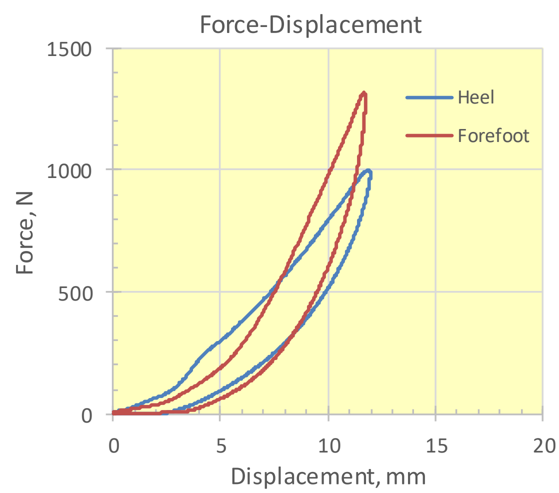
Specimen: EVA

Thickness HL: 30.0 mm
FF: 21.1 mm

Results:

		Test #	Ein J	g-max g	x-max mm	t-max ms	Eret %	k kN/m	CE	n
Heel	Mean	9610	5.01	12.0	12.0	16.1	56.4	88.3	0.167	1.39
	sd		0.01	0.0	0.1	0.1	0.2	0.7	0.000	0.02
Forefoot	Mean	9611	5.00	15.8	11.7	14.8	57.1	156.3	0.180	2.09
	sd		0.01	0.0	0.2	0.2	0.2	0.8	0.000	0.05





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Footwear Impact Test Results

Client:	Protalus	Test Date:	
Attn:	Chris Buck	Report Date:	
Project	Protalus Insole Comparisons	Authors:	MS / EP

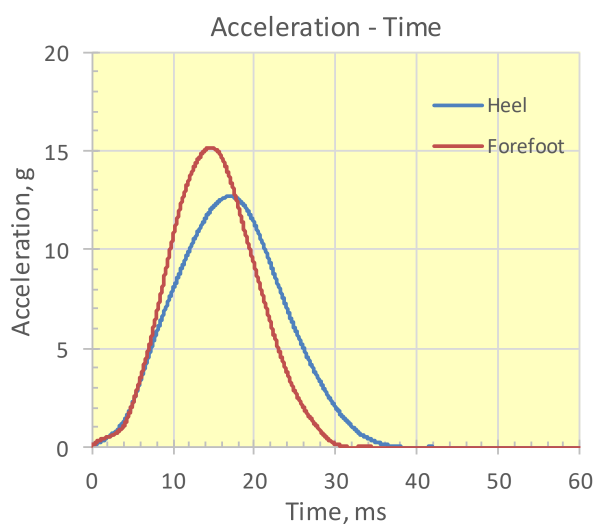
Method: ASTM F1976-13 Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials
https://www.astm.org/Standards/F1976.htm

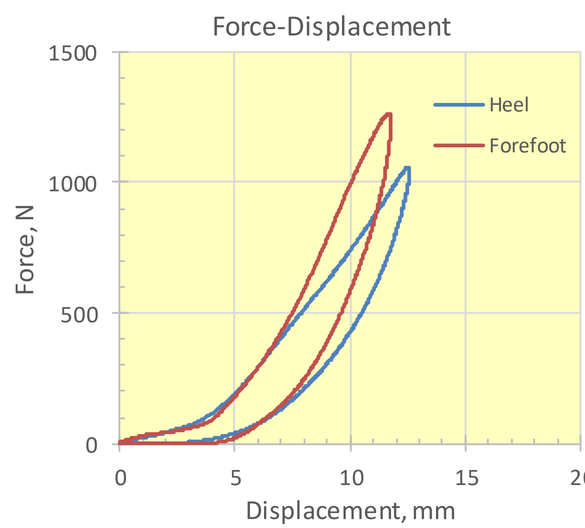
Specimen: Superfeet

Thickness HL: 34.7 mm
FF: 29.7 mm

Results:

		Test #	Ein J	g-max g	x-max mm	t-max ms	Eret %	k kN/m	CE	n
Heel	Mean	9612	4.99	12.7	12.6	17.0	54.7	100.5	0.136	1.67
	sd		0.02	0.0	0.1	0.1	0.2	1.0	0.000	0.02
Forefoot	Mean	9613	5.02	15.1	11.7	14.7	52.3	145.2	0.134	1.97
	sd		0.01	0.0	0.1	0.0	0.1	0.7	0.000	0.01





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Footwear Impact Test Results

Client:	Protalus	Test Date:	
Attn:	Chris Buck	Report Date:	
Project	Protalus Insole Comparisons	Authors:	MS / EP

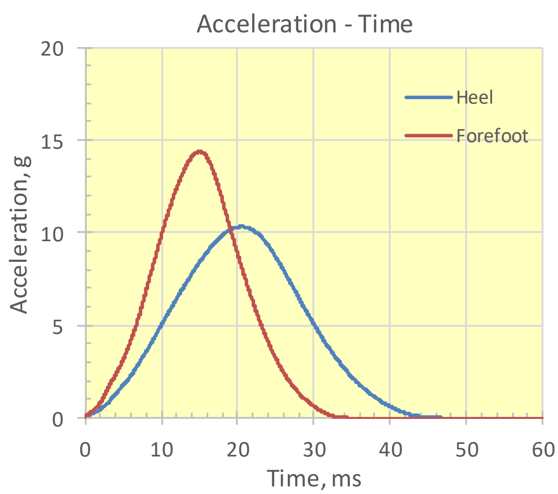
Method: ASTM F1976-13 Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials
https://www.astm.org/Standards/F1976.htm

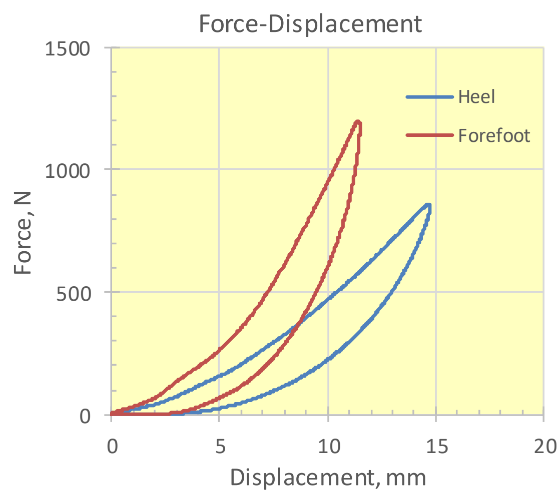
Specimen: M100

Thickness HL: 37.7 mm
FF: 24.2 mm

Results:

		Test #	Ein J	g-max g	x-max mm	t-max ms	Eret %	k kN/m	CE	n
Heel	Mean	9614	4.99	10.3	14.8	20.5	55.0	66.5	0.154	1.54
	sd		0.01	0.0	0.1	0.0	0.2	0.3	0.000	0.01
Forefoot	Mean	9615	4.99	14.4	11.5	15.0	52.4	128.5	0.172	1.76
	sd		0.02	0.0	0.1	0.1	0.1	1.1	0.001	0.01





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Footwear Impact Test Results

Client:	Protalus	Test Date:	
Attn:	Chris Buck	Report Date:	
Project	Protalus Insole Comparisons	Authors:	MS / EP

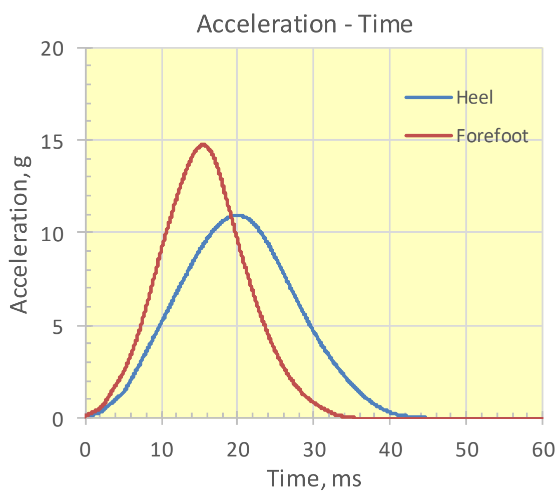
Method: ASTM F1976-13 Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials
https://www.astm.org/Standards/F1976.htm

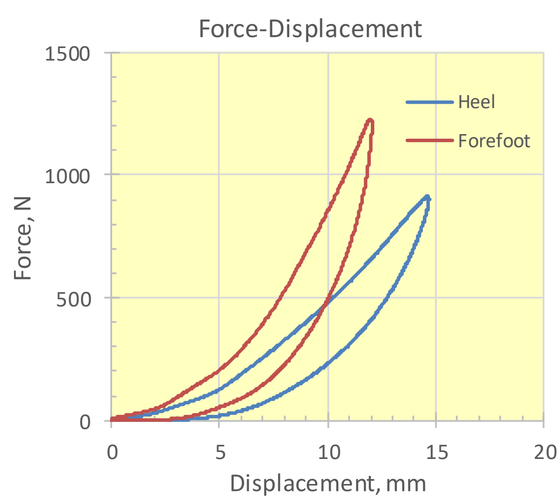
Specimen: T100

Thickness HL: 34.5 mm
FF: 24.5 mm

Results:

		Test #	Ein J	g-max g	x-max mm	t-max ms	Eret %	k kN/m	CE	n
Heel	Mean	9616	4.99	11.0	14.7	20.0	55.8	74.6	0.158	1.69
	sd		0.03	0.0	0.2	0.2	0.2	0.3	0.000	0.04
Forefoot	Mean	9617	4.98	14.8	12.1	15.5	53.3	136.0	0.165	1.98
	sd		0.01	0.0	0.0	0.0	0.1	0.5	0.000	0.01





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Appendix 3: Subject Characteristics

Subj	Sex	Age	Mass	Stature	BMI	Shoe Size		Walking Speed	
#		y	kg	cm	kg m^{-2}	US		mph	m s^{-1}
1	M	28	70.9	180	21.8	M	11	2.9	1.30
2	M	17	50.0	170	17.3	M	9	2.5	1.12
3	M	25	81.8	191	22.5	M	12	2.4	1.07
4	M	29	116.4	185	33.8	M	12	2.9	1.30
5	M	26	82.7	180	25.4	M	11	2.6	1.16
6	M	30	74.1	180	22.8	M	11	2.0	0.89
7	M	29	72.7	178	23.0	M	9	2.2	0.98
8	M	64	116.4	178	36.8	M	11	1.2	0.54
9	M	50	96.8	183	28.9	M	11	2.9	1.30
10	M	29	69.5	175	22.6	M	10	2.0	0.89
11	M	34	101.4	173	34.0	M	11	1.8	0.80
12	M	38	71.8	180	22.1	M	9	2.1	0.94
13	M	24	65.7	170	22.7	M	10	1.8	0.80
14	M	37	68.6	173	23.0	M	11	1.8	0.80
15	M	31	80.5	169	28.2	M	11	2.1	0.94
16	M	48	94.5	184	27.9	M	11	2.5	1.12
17	M	24	66.4	180	20.4	M	11	2.2	0.98
18	M	56	71.8	183	21.5	M	12	1.6	0.72
19	M	29	110.5	188	31.3	M	12	2.1	0.94
20	M	28	89.5	180	27.5	M	12	2.3	1.03
21	M	24	81.4	180	25.0	M	10	2.6	1.16
22	M	34	111.4	173	37.3	M	11	2.1	0.94
23	M	51	71.8	183	21.5	M	11	2.1	0.94
24	F	42	95.5	182	28.9	W	9	1.6	0.72
25	M	63	70.9	165	26.0	M	9	2.3	1.03
26	F	42	60.0	168	21.3	W	8	1.7	0.76
27	F	31	62.7	178	19.8	M	10	1.3	0.58
28	M	21	84.5	185	24.6	M	12	2.1	0.94
29	F	25	62.3	173	20.9	W	8	2.6	1.16
30	M	29	68.2	179	21.3	M	10	3.0	1.34
31	F	20	61.4	166	22.2	W	8	2.1	0.94
32	M	67	81.8	178	25.9	M	9	1.9	0.85
33	M	66	73.6	183	22.0	M	10	2.3	1.03
34	F	60	75.0	170	25.9	W	8	1.8	0.80
35	M	46	83.6	174	27.6	M	10	2.0	0.89
36	F	69	78.6	173	26.4	W	10	1.8	0.80
37	F	57	70.5	168	25.1	W	10	1.9	0.85
38	M	27	79.5	187	22.8	M	12	2.2	0.98
39	F	26	63.6	165	23.3	W	9	1.9	0.85

Appendix 4: Mean Peak Plantar Pressure (kPa) by Region and Subject

	Heel				Midfoot				MTP			
Subj	**EVA**	**S'Feet**	**M100**	**T100**	**EVA**	**S'Feet**	**M100**	**T100**	**EVA**	**S'Feet**	**M100**	**T100**
1	255	265	231	221	79	69	21	31	145	159	138	138
2	307	241	290	290	62	69	69	62	193	179	210	224
3	234	207	234	120	100	117	100	107	224	224	217	241
4	234	203	234	124	134	159	183	172	262	241	365	262
5	448	376	427	362	100	100	72	66	310	359	331	293
6	152	138	159	155	55	59	48	66	169	159	148	162
7	248	210	245	214	79	176	90	148	510	607	517	452
8	231	200	286	224	83	100	162	93	583	603	462	496
9	262	269	290	252	72	100	62	121	259	317	314	286
10	355	252	286	307	86	66	69	100	159	200	214	186
11	272	279	314	262	100	121	107	197	265	279	296	241
12	286	262	314	293	48	76	59	48	300	334	293	283
13	221	210	234	221	179	155	176	207	338	317	303	307
14	310	255	286	283	90	90	55	69	252	441	296	262
15	310	255	272	307	179	214	221	210	310	314	310	255
16	372	345	365	314	162	159	138	148	531	472	448	517
17	200	165	255	176	107	148	79	107	345	393	310	276
18	259	255	286	265	69	103	72	83	221	248	228	238
19	272	238	269	265	169	217	186	207	445	438	465	403
20	386	328	372	328	124	231	183	190	307	359	390	310
21	390	465	424	421	193	321	252	217	359	452	372	441
22	179	186	176	214	97	100	107	110	228	245	214	252
23	290	224	231	248	66	103	83	62	217	224	165	183
24	396	307	269	328	62	210	134	176	310	503	462	372
25	255	207	190	214	117	162	100	110	279	255	238	310
26	265	197	224	255	186	83	210	207	255	324	252	279
27	265	262	262	238	190	221	190	165	479	631	479	441
28	176	224	203	217	100	134	152	193	303	390	334	348
29	328	296	303	341	131	107	93	69	655	696	469	503
30	296	324	283	269	79	55	48	34	197	159	145	145
31	283	269	245	276	66	107	72	86	400	403	348	365
32	286	228	234	245	148	165	117	110	186	210	165	197
33	469	434	403	476	138	165	72	121	510	593	365	379
34	228	224	183	197	103	190	134	131	469	548	383	503
35	276	200	228	207	93	93	97	69	245	203	231	217
36	176	165	138	134	162	210	238	186	296	276	252	307
37	279	231	207	241	300	369	393	331	465	479	386	410
38	190	190	165	169	100	117	148	100	172	193	183	183
39	190	165	162	193	69	62	62	66	293	272	276	279

Appendix 5: Mean Peak Plantar Pressure Rate (MPa s^{-1}) by Region and Subject

	Heel			
Subj	EVA	S'Feet	M100	T100
1	84	77	78	77
2	54	58	63	49
3	72	63	60	65
4	72	60	63	61
5	103	76	94	69
6	75	55	75	56
7	62	60	51	75
8	52	61	83	67
9	71	67	46	37
10	55	99	64	43
11	85	39	99	73
12	66	37	33	30
13	69	24	33	53
14	83	40	40	36
15	79	42	59	75
16	48	58	46	38
17	52	62	47	45
18	48	39	50	46
19	42	38	58	59
20	84	72	77	44
21	74	49	34	64
22	50	65	66	63
23	61	66	52	54
24	30	30	23	29
25	91	75	37	44
26	26	35	24	31
27	53	58	36	40
28	55	35	27	26
29	48	86	32	42
30	72	62	53	56
31	73	47	33	35
32	77	56	38	47
33	52	50	66	54
34	55	62	61	47
35	67	48	68	58
36	41	68	35	44
37	23	46	46	45
38	46	27	35	27
39	50	38	33	38
Mean	62	55	52	50
sd_1	18	17	19	14
sd_2	6	6	5	5

Among Subjects (sd_1)
Within Subjects (sd_2)

Appendix 6: Subjective Ratings

Subjects' reported ratings on a 1-7 scale.

	Comfort				Support				Balance			
Subj	**EVA**	**S'Feet**	**M100**	**T100**	**EVA**	**S'Feet**	**M100**	**T100**	**EVA**	**S'Feet**	**M100**	**T100**
1	4	5	6	6	5	6	6	6	6	6	7	7
2	4	6	4	6	3	7	4	6	3	6	5	6
3	3	4	3	5	2	4	3	5	3	3	4	5
4	2	2	4	4	3	3	4	4	4	4	5	4
5	3	3	6	6	3	4	6	7	3	4	5	7
6	3	3	6	6	3	5	5	4	3	2	6	5
7	6	5	4	5	4	6	6	3	5	7	5	7
8	6	6	4	3	6	5	6	4	6	5	4	4
9	4	4	3	2	3	4	2	3	4	3	3	2
10	6	5	7	6	6	5	7	6	6	6	6	6
11	4	3	5	5	3	5	4	4	3	5	3	5
12	4	5	6	5	4	5	7	4	4	3	6	4
13	4	3	5	5	4	4	5	5	5	5	5	5
14	4	5	5	5	3	3	4	5	4	4	5	5
15	6	5	4	3.5	5	5	4	3.5	5	5.5	3.5	4
16	5	6	5	4	3	4	5	3	3	4	6	3
17	4	6	5	5	2	6	3	5	3	5	6	5
18	3	4	5	4	2	4	4	5	4	4	4	5
19	4	4	5	6	4	4	4	5	4	4	5	6
20	6	5	4	5	6	4	3	5	5	4	3	5
21	3	4	3	5	3	5	4	5	4	4	3	5
22	7	4	3	4	6	4	5	5	5	6	6	6
23	4	7	5	6	4	7	5	6	5	6	6	6
24	6	5	4	5	6	6	4	4	6	6	2	5
25	3	3	6	6	3	4	6	6	4	3	6	6
26	6	6	6	5	6	6	6	5	5	6	6	4
27	4	4	7	3.5	4.5	5	6.5	4	5	5	6	4.5
28	6	5	5	7	5	6	6	7	7	7	3	7
29	4	5	6	6	3	5	5	6	4	4	4	6
30	5	4	6	6	4	3	5	4	4	3	4	4
31	6	2	7	7	5	4	7	6	4	4	4	4
32	4	5	7	3	2	6	6	5	2	5	6	5
33	4	3	4	4	3	5	4	4	4	4	4	4
34	6	5	6	6	5	7	5	5	4	6	5	5
35	4	6	5	6	3	6	5	6	4	7	6	6
36	4	4	5	5	4	4	5	4	3	5	6	4
37	4	2	5	5	4	3	5	3	4	3	5	7
38	1.5	2	6	5	1	1	4	5	3	3	4	6
39	6	7	6	4	6	7	6	3	5	7	6	4
Mean	4.4	4.4	5.1	5.0	3.9	4.8	4.9	4.8	4.2	4.7	4.8	5.1
sd	1.3	1.4	1.2	1.1	1.4	1.3	1.2	1.1	1.1	1.3	1.2	1.2

Appendix 7: Static Alignment

Measurements are degrees of pronation from neutral reference.

	Tibia vs Heel				Tibia vs Arch			
Subj	**EVA**	**S'Feet**	**M100**	**T100**	**EVA**	**S'Feet**	**M100**	**T100**
3	9.1	5.7	3.6	6.3	5.5	5.2	7.1	3.1
4	20.1	12.5	3.4	4.1	15.0	12.6	5.5	2.8
5	9.0	7.8	3.4	6.0	13.1	11.1	3.9	3.2
6	11.7	9.9	8.2	9.0	5.2	5.1	9.3	4.9
7	10.3	8.0	4.1	5.2	4.7	5.0	6.2	2.7
9	8.7	7.5	4.2	5.2	5.1	7.5	4.9	3.0
10	8.3	5.9	2.8	4.8	6.7	6.6	4.3	3.3
11	11.3	6.5	4.3	4.9	5.7	5.4	3.9	3.0
12	8.2	5.9	3.0	4.4	5.9	7.1	5.1	3.3
13	22.3	16.2	4.5	9.8	14.5	14.9	7.5	4.4
14	6.7	7.5	3.5	5.7	4.9	6.3	4.3	3.1
15	11.4	7.7	4.7	5.3	6.3	6.0	4.5	2.7
16	9.0	6.6	5.1	6.5	7.1	7.4	5.6	3.5
17	9.3	6.5	3.7	5.8	7.3	6.2	4.4	3.0
18	9.5	10.3	4.5	5.0	7.0	7.6	5.4	2.5
19	8.4	8.1	4.2	4.7	5.8	6.9	4.0	3.4
20	15.4	7.2	3.2	4.8	5.9	6.8	4.8	3.0
22	2.8	1.7	1.8	2.8	3.4	0.7	3.1	2.1
23	7.4	6.6	0.7	2.5	2.5	2.8	0.5	1.2
25	12.4	10.9	2.9	8.7	3.9	4.5	3.6	2.3
26	4.2	3.9	1.4	3.5	1.7	1.2	0.2	0.5
28	8.1	5.7	2.1	3.2	2.2	4.3	3.0	1.3
29	6.1	6.3	3.3	5.5	5.1	7.2	3.9	2.9
31	9.5	1.2	1.0	1.9	8.2	0.2	1.4	0.4
32	7.2	5.2	2.7	4.5	5.2	3.8	3.2	2.1
34	6.2	7.2	3.0	4.9	4.0	4.3	3.7	2.4
35	8.4	6.7	1.1	6.2	4.3	2.7	0.3	2.2
36	5.5	3.4	2.3	4.3	3.9	2.6	4.0	2.3
37	4.8	2.3	1.1	2.3	2.6	3.0	0.4	1.7
38	6.4	3.3	3.3	4.1	1.3	1.5	1.4	1.1
39	6.3	5.6	2.6	3.6	4.7	4.4	3.5	2.0
Mean	9.2	6.8	3.2	5.0	5.8	5.5	4.0	2.6
sd	4.1	3.1	1.5	1.8	3.3	3.3	2.1	1.0