AN ABSTRACT OF THE THESIS OF

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A measurement system has been developed to continuously record pressure data between the sole of the foot and the shoe. Five force sensing resistors are mounted to an insole suitable for shoe insertion. The sensors are located at the heel, toe and under three metatarsal heads. Data from the sensors are transferred to a host computer via a Universal Serial Bus (USB) cable and saved to system memory. The system is capable of sampling data up to 240Hz across 5 active data acquisition channels. Software uses the data to display the loading profile for each sensor in order to provide quantitative results of cumulative plantar pressure. The history of each sensor can be acquired to examine event related alterations, such as endurance sport events or pre and post surgical procedures. The system is designed with the capability to supply the data necessary for characterization of such alterations.

An In-shoe Instrument for Acquisition and Storage of Plantar Pressure

by
Heidi P. Noce

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An In-shoe Instrument for Acquisition and Storage of Plantar Pressure

INTRODUCTION

Portable devices to measure, store, and analyze in-shoe plantar pressures have emerged over the last decade as useful tools in research, clinical and product development applications. A few commercially available systems, such as F-scan (Tekscan, Boston,MA, USA) and Pedar (Novel, St Paul, MN, USA), have been used for their wide pressure measurement ranges and large number of pressure sensors (F-scan = 960/foot, Pedar = 256/foot) in the insole. However, this functionality is expensive (>$10,000). The accuracy and precision of these insoles also varied among levels of applied pressure, calibrations, duration of applied pressure, and how much the insole was used over time (Hsiao et al., 2002).

Research institutions have been developing insole pressure measurement devices specific to their needs with simple component systems. In 1997, Abu-Faraj et al. developed a portable insole plantar pressure measurement system that recorded pressure-time data for 8 hours from 14 site-specific pressure sensors at a 40Hz sampling frequency. In 2000, Pataky et al. desired additional functionality and reconfigured the system to record for 8 days with a feedback warning alarm for high and low plantar pressure in diabetic patients. In 2001, Morley et al. developed a portable, in-shoe, multisensory data acquisition system to simultaneously record pressure, temperature and humidity. The system was capable of recording pressure data from 4 sensors at a rate of 30Hz for 4.5 hours. In addition, 2 temperature sensors and a humidity sensor were sampled once per minute. Although the reliability and validity of this system was deemed acceptable (Maluf et al., 2001), the pressure sensors used were a costly $200 each.

The pressure systems that have been briefly described have been characterized as portable instruments. The portability consisted of having a typical user wear an electronics module on a hip belt or attached to the ankle or calf for many hours throughout the day. A flex cable extended from the electronics module and connected to the pressure sensors in the insole. Sensor data were stored in memory until they were downloaded to computer. Many of these systems were developed to aid patients with diseases that made them susceptible to unnoticed trauma on the foot, such as diabetes or peripheral neuropathy. This required many hours of wearing a "portable" device that was likely to alter gait over time. In 2001, Kirtley developed a portable, instrumented insole that had sensors, electronics and battery power mounted to the insole, which enabled the user to be free of body-mounted electronics modules or battery packs. The self-contained unit could output data, record to memory and subsequently download by telemetry. Because Kirtley was interested in measuring simultaneous kinetic (pressure) and kinematic (motion) gait parameters in order to quantify ankle push-off during walking (2001), a gyro sensor was included in the system to measure ambulatory movement of the foot. Kirtley has developed something unique compared to the systems currently available because his device does not require any external packs that must be worn somewhere on the body. All necessary components are built into the insole. Perhaps this new development will change what is expected from future portable, plantar pressure measurement devices.

Many pressure measure systems exists that have been developed for the specific needs of a research group. The commercially available devices have greater functionality, however they come with a high cost. The purpose of this research project was to take the first steps into developing a low-cost insole, pressure measurement system that can detect event related alterations during endurance sports or pre and post surgical procedures. The first stage of this research focuses on sensor selection, low cost analog-to-digital conversion, software development, and development of a data acquisition system capable of collecting pressure-time data of sufficient rate and duration. Although not a requirement of this first stage of development, the ultimate goal is to develop a fully portable system once the initial development challenges are understood.

METHODS

Acquisition System Design

The data acquisition system (Figure 1) consists of 5 Inastomer pressure sensors (Model IESF-R-5, CUI Inc., Beaverton OR) that are fitted to the underside of a SPENCO® insole. The sensors are connected, via a flexible cable, to an electronics module. The module consists of 5 low-voltage operational amplifiers (NTE 857M, Bloomfield NJ), a low-cost USB-based, eight-channel, 12-bit analog-to-digital converter (Measurement Computing PMD-1208LS, Middleboro MA) and other interfacing circuitry. Sensor output can be sampled at a rate up to 240Hz. Data are collected, processed, and stored with an Intel Pentium III microprocessor notebook computer (Compaq Presario 1200) and a custom interface program (SoftWIRE MCC DAQ Controls for VB6, V3.1, Middleboro MA). The computer is also used for power supply and visual output.

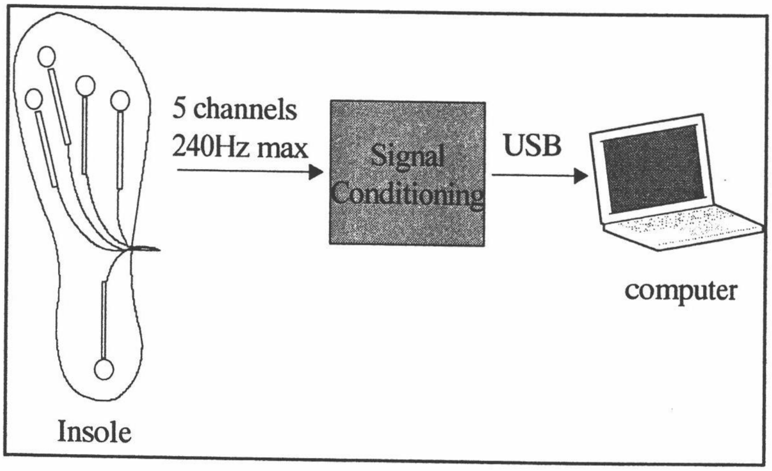


Figure 1. Diagram of the data acquisition system

Pressure Sensors

The CUI pressure sensors were selected to measure in-shoe plantar pressure because of their electronic simplicity, low cost ($4.80 each for a quantity of 50), thin sensing element, and ability to mount on bent or curved surfaces. The CUI pressure sensors have an 8 mm active diameter that is made of a flexible, conductive, elastomer-based composite. The composite contains carbon molecules which, when altered due to compression, torsion, elongation or bending, cause the conductivity of the material to increase in proportion to the magnitude of the applied force. The sensor has a maximum load rating of 4.0 kg, which is equivalent to 780kPa with an active diameter of 8 mm. A literature review helped determine whether this specification was sufficient for the purposes of the design. In 1993, Zhu et al. indicated mean peak plantar pressure values were in the range of 246 to 584kPa during walking. In 1999, Willson et al. studied the effects of fatigue while running using a sensor insole with a measurement range of 0-600kPa. If this range was sufficient for Willson's research with running participants, perhaps the CUI sensor would be sufficient for the system to be developed for this study.

The following table is a list of the IESF-R-5 sensor specifications:

Table 1. Pressure sensor specifications

Maximum load:	4.0kg (~780kPa)
Recommended load:	1.5kg (~292kPa)
Life:	≥100,000 cycles @100g (1 second ON/3 seconds OFF)
Operating Temp:	+10° to 40° C
Storage Temp:	-40° to 70° C
Response:	≤6μs
Humidity:	85% RH, no condensation
Current:	5mA
Maximum allowable	20mA

Sensor Placement

The pressure sensors are placed along the insole, such that they will detect force applied during the push-off and landing phases in running or walking (Figure 2). A previous study by Willson (1999) indicates the high-pressure regions to be under the heel, followed by the second and third metatarsals. For this study, 5 sensors were located at the heel (H), first metatarsal head (M1), second metatarsal head (M2), third metatarsal head (M3), and hallux or big toe (BT).

Insole Instrumentation

A standard SPENCO® Insole that is 3-4 mm thick was used to house sensors and connecting wires into channels that were carefully carved out of the lower insole material. To ensure that subjects did not perceive the sensors or wires, channels were carved deep enough that wires and sensors were flush-mounted to the lower insole material. A highly heat resistant tape was used to hold sensors and wires in place.

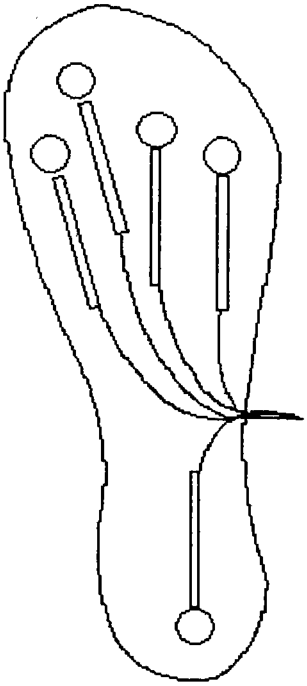


Figure 2. Sensor placement on insole

Signal Conditioning and Digitization

Signals from the pressure sensors were amplified using 5 NTE 857M operational amplifiers. Output signals from these amplifiers ranged from approximately 1.32 - 4.375 Volts with a resolution of 1mV. Figure 3 displays the pin diagram of the op-amp. The signal from a pressure sensor is supplied to pin 3 and the amplified signal exits at pin 6. Power was supplied to the op-amp at pin 7 from the laptop computer via Universal Serial Bus (USB).

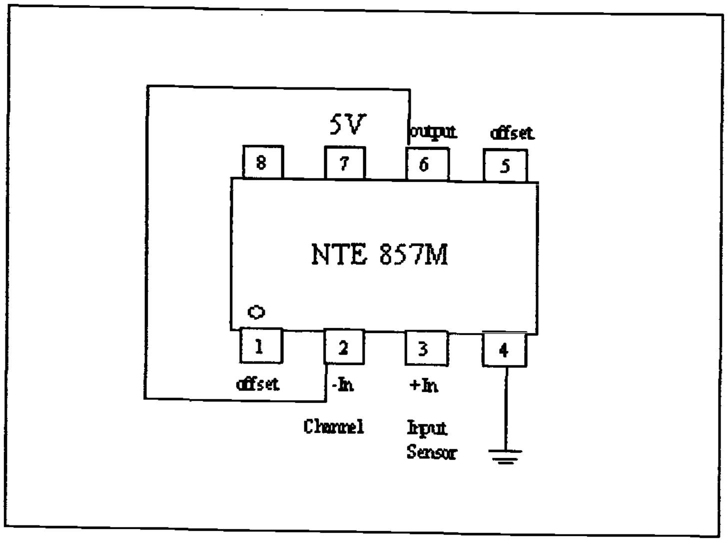
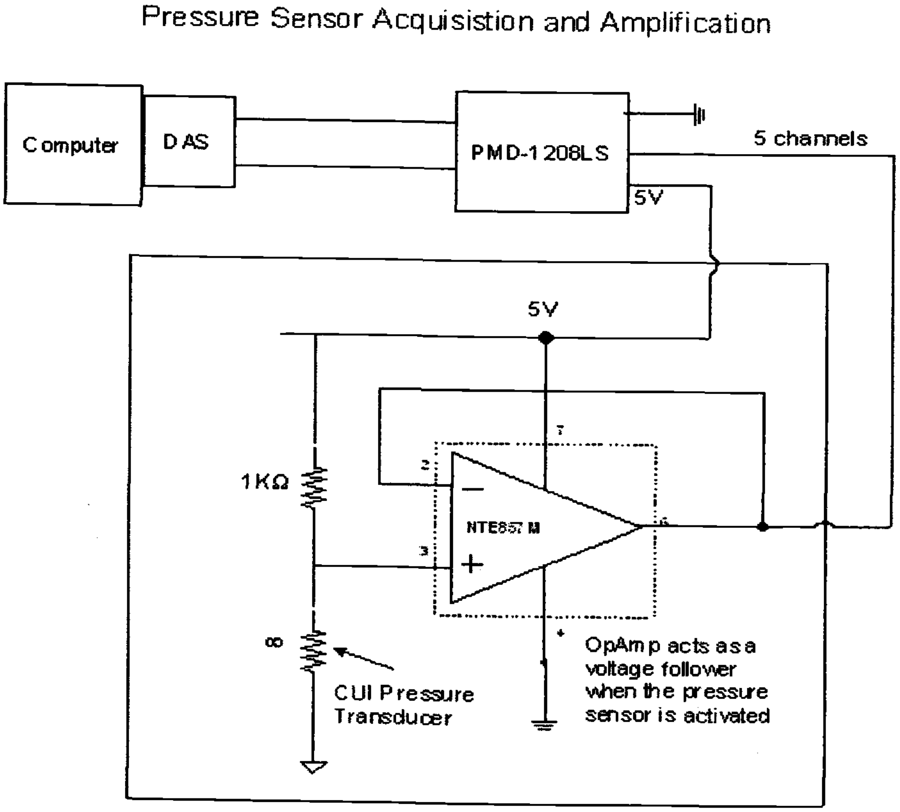


Figure 3. Schematic diagram of the NTE857M operational amplifier circuit.

Once the pressure sensor signals are amplified, the PMD1208LS device converts data from analog to digital and transmits the data to the computer via USB. The resulting data are collected and stored to a file in the computer. The advantage of using a USB cable is that the analog data acquisition and conversion can be done near the source (pressure sensors). Once the conversion is done, digital data can be transferred over large distances without any loss in accuracy. Analog signals transferred over long distances can be subject to inaccuracies due to voltage drop (resistive, capacitive and inductive), external electrical noise, ground currents, contact resistances in the path, and cross-talk. These inaccuracies would inhibit the pressure sensors' ability to accurately observe a change.

Figure 4 shows the schematic of the data amplification and acquisition process. Signals from the 5 pressure sensors can be sampled serially at a maximum of 240 Hz for each channel. For Paradiso (1998), Maluf (2001) and Pataky (2000), rates between 30 and 100Hz were used during walking. For higher speed activities, such as running, sampling frequencies of 200Hz or greater are often required (Orlin, 2000).



OpAmp acts as a voltage follower when the pressure sensor is activated

Figure 4. Diagram of pressure sensor amplification and acquisition system

Apparatus

Two testing machines were used to test the capabilities of the pressure measurement insole. The Instron materials testing machine (5567, Canton MA) was used to apply known pressure onto a specific pressure sensor to determine changes in sensor output after cyclic testing and after exposure to elevated temperatures. The EnduraTEC (ELF 3200, Minnetonka MN) was used to apply pressure at different frequencies in order to establish the response characteristics of the pressure measurement system (Figure 5). In addition, this machine was used to verify other sensor specifications such as linearity, capacity, hysteresis and sensitivity. The EnduraTEC applies load in a manner similar to the Instron, however, half-way through the project, there was a need to apply cyclic load at frequencies that were not suited for the Instron. In addition, during initial testing, it was difficult to control the applied load with the Instron due to the low loads that were being used. The EnduraTEC has the ability to apply low loads at much higher frequencies.

Butterworth filtering (Winters) was used to smooth the raw Instron data in order to identify peak pressure values with more accuracy. The output data of the applied load by the Instron was not as smooth as the EnduraTEC data even with the same data collection rates.

To test the response time of the sensors, a Tektronix 2211 Digital Sampling Oscilloscope (2211, Beaverton OR) was used to capture the sensor voltage output before amplification and acquisition. These data were compared with the voltage output recorded by a custom program that was developed to store data and provide visual output after acquisition. This program was developed in Visual Basic (Microsoft, V6.0) using the SoftWIRE (Measurement Computing, V3.1) program. A wire diagram of the program modules used in the software is included in Appendix A.

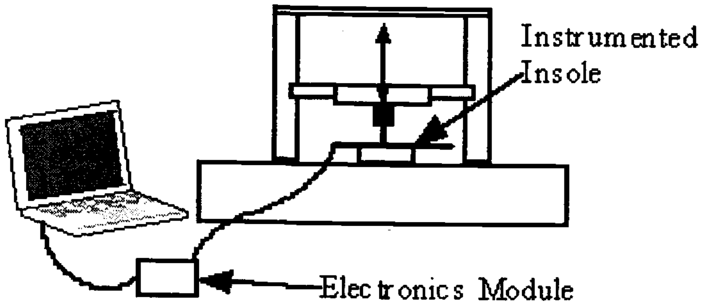


Figure 5. A schematic of the EnduraTEC with the instrumented insole

System Characterization

The plantar pressure measurement system is characterized by six parameters: capacity, sensitivity, linearity, hysteresis, frequency response, and signal response. The accuracy and reliability was also characterized by testing the ability to measure average pressure, the performance over time, and the performance at elevated temperatures. The six parameters and the ability to measure average pressure were determined by running an array of tests using the EnduraTEC high-frequency testing machine. This machine was calibrated before and after each testing session. The performance parameters were tested using the Instron high load tester.

Because the pressure sensors output a voltage when pressure is applied, it was necessary to characterize this output in units of pressure. This was accomplished by using a static loading calibration procedure. Static calibration consisted of using the EnduraTEC test machine to apply nine different loads to one sensor. The diameter of the pellet used to load the sensor was 8mm, which provided a pressure range between 98 and 467kPa. Each pressure was applied in random order for about 1 minute, or until a stable reading could be achieved. The corresponding voltage output was recorded and pressure was released for at least 1 minute until the next recording. Linear regression was used to determine the best-fit equation of applied pressure to voltage output.

When a subject ambulates, whether he or she is are walking or running, the forces on the insole are changing over time. In order to characterize how the insole responds to this kind of loading, dynamic testing was also performed. During the stance phase (foot contact) of running, the foot makes contact with the ground for about 0.2 seconds, depending on the speed of the participant (Frederick, 1986). In 1981, Elliot and Ackland et al. studied 8 participants in a 10-kilometer race with stride rates between 3.03 to 3.13 steps per second. In 1980, Elliott and Roberts studied 8 running participants in a steady-pace, 3000-meter run with stride rates between 3.04 and 3.10 steps per second. The stride rates from these studies are considering both feet. For the insole being developed in this study, an equivalent stride rate for one foot would be 1.5Hz. However, a running stride was simulated by applying a sinusoidal load to the sensor at a rate of 6Hz. A moderate rate was desired in order to not under-stress or over-stress the system. This rate was practical for the purposes of this design and was a midpoint of what could be expected in the frequency kinematics of running. A total duration of 3-minutes was incorporated because initial data indicated the pressure sensors were taking about one minute to stabilize. The remaining 2-minutes were used to collect a sufficient amount of data. Simulating a high-speed activity, such as running, was desired in order to properly stress the measurement system in a typical-case scenario.

To determine the maximum pressure the system could measure (capacity), a pressure of approximately 100kPa was applied to one sensor until the voltage output was stable. After recording the corresponding voltage, the process was repeated with an increase of approximately 40kPa in the applied pressure. These applied pressure increments continued until it was clear that the sensor output was not changing.

The sensitivity and linearity of the system could be determined by using the best-fit equation from the static calibration procedure. The sensitivity is the slope of the line. For this pressure measurement system can be defined as the measure of how much the output of a sensor changes as the input pressure changes. Results are expressed in volts per unit of pressure (Pascals). Linearity is a measure of how far the output varies from a straight line. The equation used for calculating linearity is shown in Figure 6. Results were expressed as a percent of the full-scale output.

$$\text{Linearity} = \frac{(\text{Ymax} - \text{Ymin})\ \text{trendline}}{(\text{Ymax} - \text{Ymin})\ \text{actual applied pressure}}$$

Figure 6. Linearity equation

The insole used in the design of this pressure measurement device is made of a neoprene-like material that is very flexible. The energy absorbed by the material can be estimated by determining the greatest difference between the performance of the sensor during loading and unloading. This is referred to as hysteresis of the system, which is expressed in percent of full-scale output.

To create a hysteresis curve, the sensor was loaded in 3 steps from 100kPa to a maximum of 405kPa, and back down again in the same 3 steps. At each load change, the load was held for 1 minute until the voltage output from the sensor stabilized.

Frequency Response

Because ambulatory movement is a dynamic activity, it is important to know the frequency response of the device. In other words, how does the rate of the applied load affect the accuracy of the measure pressure? This was determined by applying a sinusoidal load with an amplitude of 400kPa at low frequency. The amplitude of the corresponding sensor output signal was recorded after approximately 1 minute when the peak-to-peak amplitude of the sensor signal was consistent. The process was repeated with the same load amplitude at a number of other, higher frequencies. Sensor output data at the different frequencies were evaluated by calculating the ratio of the peak pressures of the applied signal to the peak pressure computed from the sensor output at each frequency level.

Signal Response

The design of a data acquisition for this system can be set up to sample data from the pressure sensors in two different ways. The first is to collect data from all acquisition channels at the same instant. The second is to sample data serially across all channels. The amplification and acquisition process that has been designed incorporates the latter. Five sensors are connected to five channels in the acquisition system and all the sensors are sampled serially. This means that the pressures signals from the sensors are not sampled simultaneously. In order to determine if the pressure signals need to be synchronized to avoid signal distortion, a test to compare the response of a pressure sensor before and after acquisition was performed. A Tektronix 2211 Digital Sampling Oscilloscope was used to capture the pre-acquisition voltage signal from a pressure sensor being loaded at a rate of 3 Hz. The post-acquisition sensor signal was recorded at the same time using the custom program developed to store and display the sensor output in voltage units. These two signals were compared graphically to check for data mismatch.

A limitation of this test that is worthy of note at this point is that the data collected by the two methods described are not synchronized by time. This creates an assumption that there is no time lag in data collection after acquisition.

Ability to Sense Average Pressure

Because the material properties of the insole and sensor are different, it is important to determine if the pressure applied over a specified area is the same as the pressure measured with the sensor. Three cylindrical loading pellets of different diameters were used to apply approximately 400kPa to the pressure sensor using different combinations of load and area. The loading pellets were sized to be larger (12.7mm), smaller (6.3mm) and approximately the same size (7.92mm) as the pressure sensing area. The pressure sensor has an 8 mm sensing area that rests under a protective elastomer cover. During testing, the pellet was centered over the sensor carefully in order to ensure that the pressure applied was covering the entire sensing area. The load was held on the sensor for at least 1 minute until the corresponding sensor output stabilized. The sensor output was recorded for 6 to 7 trials at each pellet size. Using the linear regression equation determined from static calibration, the average sensor output was converted to pressure units.

Reliability Testing Procedures

To assess the reliability of the pressure measurement system over time, the Instron testing machine was used to apply a triangular load to one sensor. Testing proceeded for a total of 1 hour and sensor output data were sampled at

10-minute intervals for 15 seconds at 200Hz. The loading rate of the Instron was programmed to 30 Newtons per second to a peak of 30 Newtons. This is roughly equivalent to a loading frequency of 0.5Hz, which is as much as the Instron could sustain for a 30 Newton peak load. Data from the Instron load cells were sampled at 100 Hz. Sampling at 100Hz provided a more manageable dataset of the applied load during this 1-hour test because it was not possible to stop data collection between the 10-minutes intervals. In addition, the rate of applied load was low compared to ambulatory activities such as running and walking, therefore a low data collection rate was reasonable. At least 5 consecutive cycles were analyzed at each 10-minute interval and the means of the peak values for load applied and sensor output were calculated. The number of peaks for each interval was 8 for the load applied and between 5 and 11 for the sensor output. To find if there were any interaction effects between loading and the time intervals, a two-factor analysis of variance (ANOVA) was performed ($p<0.05$). Because interaction effects were evident, a post-hoc Tukey test was performed to examine differences in the applied and measured pressure time groups.

Because the plantar pressure measurement insole will be used in a warm and humid environment, it is important to known whether the pressure output would be sensitive to changing temperature. A technology overview, provided by the manufacturer of the pressure sensors, indicates the Inastomer® material that is used at the heart of the sensor "becomes less conductive as the temperature rises and the output voltage diminishes accordingly." A test was performed to measure the average of peak sensor output before and after a 10-kilometer (45 minute) run by an individual with a mass of 58kg. Using the Instron, a triangular load was applied at 30 Newtons per second to a peak of 30 Newtons to each sensor before and after a 10-kilometer run. At least 6 consecutive cycles were analyzed and the means of the peak values for load applied and sensor output were calculated for the pre and post test. The mean values between pre and post testing were compared (for load applied and sensor output) for equal means with a paired, one-sided t-test ($p<0.05$). To maintain elevated temperatures after the insole was removed from the shoe, a heat lamp was mounted to the Instron and placed over the sensor. A t-type thermocouple and handheld instrument was used to verify the sensor temperature throughout testing.

RESULTS

System Characterization

Figure 7 depicts a typical calibration curve for a pressure sensor under static loading. This calibration curve was determined by applying a range of pressures between 98 and 467kPa and recording the corresponding voltage output from the sensor. When no pressure is applied, the voltage output from the sensor is approximately 4.35 Volts. For this system, when the pressure is increased, the voltage output decreases. Linear regression was used to convert voltage output to pressure in units of kilopascals.

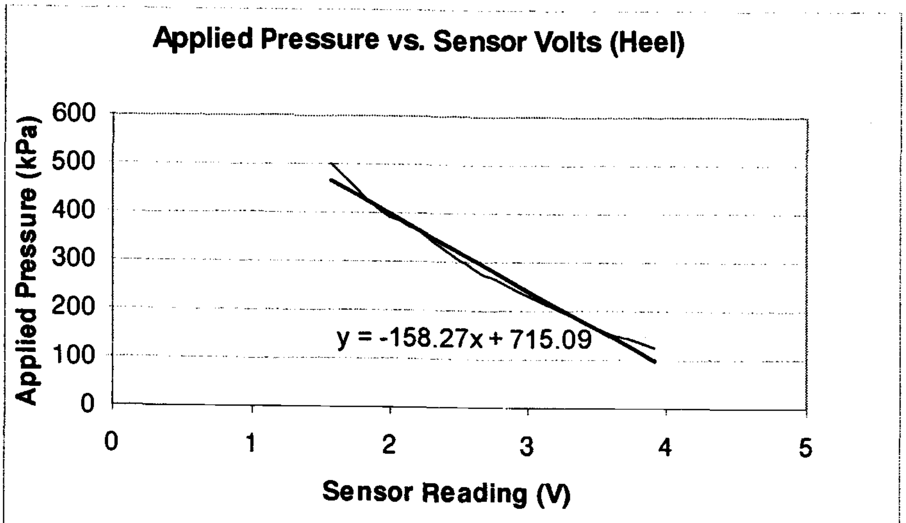


Figure 7. Applied pressure vs. voltage output of heel sensor.

Figure 8 shows a typical 1-second snippet of a comparison between the pressure applied and the sensor output during a 6Hz sinusoidal load. There is at least a 20-second warm-up period for the peak pressure signals to stabilize, therefore the snippet starts 25 seconds after dynamic loading begins. A 6Hz signal was chosen in order to properly stress the system. Stride rates during running at maximum speed can be as fast as 4.20 steps per second (Nummela, 1994). The results of the measured pressure show a clipped region at the low-pressure region of the curve. This clipping is due to the design of the data acquisition and amplification process. In order to have better resolution at high pressures, the sensor output was clipped at low pressure values.

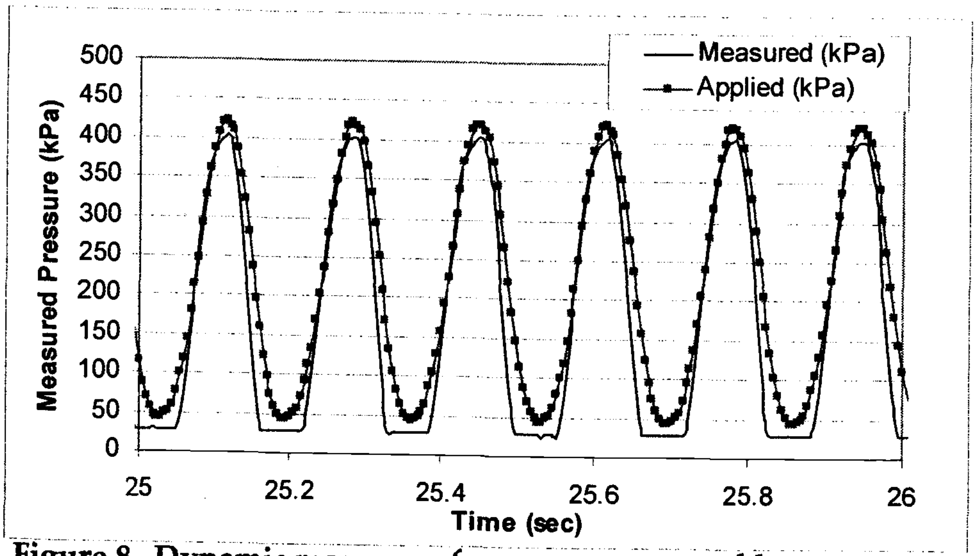


Figure 8. Dynamic response of pressure measured by sensor to pressure applied by EnduraTEC after 25 seconds of loading.

To quantify the difference between the applied pressure and the measured pressure, the average of the peak values for applied pressure and measured pressure were computed. The results were a difference of 19±2.5kPa with the applied being greater than the measured. This indicates that the system was capable of measuring pressure at 4% less than what was applied after 25 seconds of dynamic loading. However, the system seems to close this gap after 2 minutes of dynamic loading (Figure 9). The measured pressure was, on average, 9.98±7.0kPa (2%) less than the applied pressure.

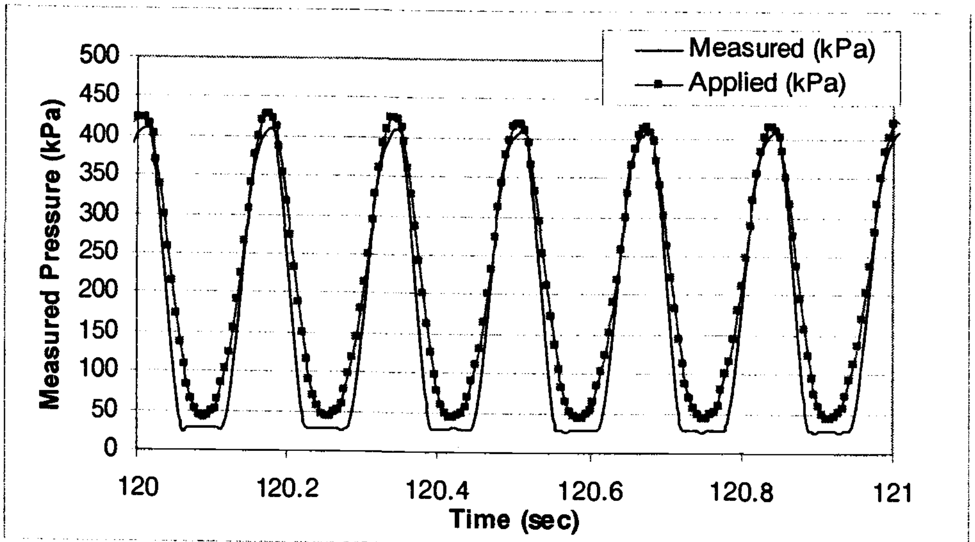


Figure 9. Dynamic response of pressure measured by sensor to pressure applied by EnduraTEC after 2 minutes of loading.

Some of the parameters determined during testing are presented in Table 2. Parameters determined by the EnduraTEC high frequency tester are compared with the parameters determined by the Instron high load tester. The outcome of the hysteresis test shows significant differences. Because of this, it is important to note that the 22.2 percent result that was acquired when testing on the Instron, was based on applied loading that was held for at least 1 minute at each load level. This was the same testing procedure that was performed using the EnduraTEC. However, the 41% result was based on a hysteresis test that held each load level for 2 minutes.

Table 2. Insole pressure measurement system specifications

	EnduraTEC	Instron
Capacity (kPa)	500	not tested
Sensitivity (mV/kPa)	6.32	9.7 - 13.0
Linearity (% Full Scale Output)	97.7	95 - 100
Hysteresis (% Full Scale Output)	7	22.2 - 41

Figure 10 depicts the amount of applied pressure to the measured pressure from the sensor. The applied pressures ranged from 150 to 1000kPa. The results show that the maximum pressure the heel sensor can measure is 500kPa, which is much less than the 780kPa specified by the manufacturer.

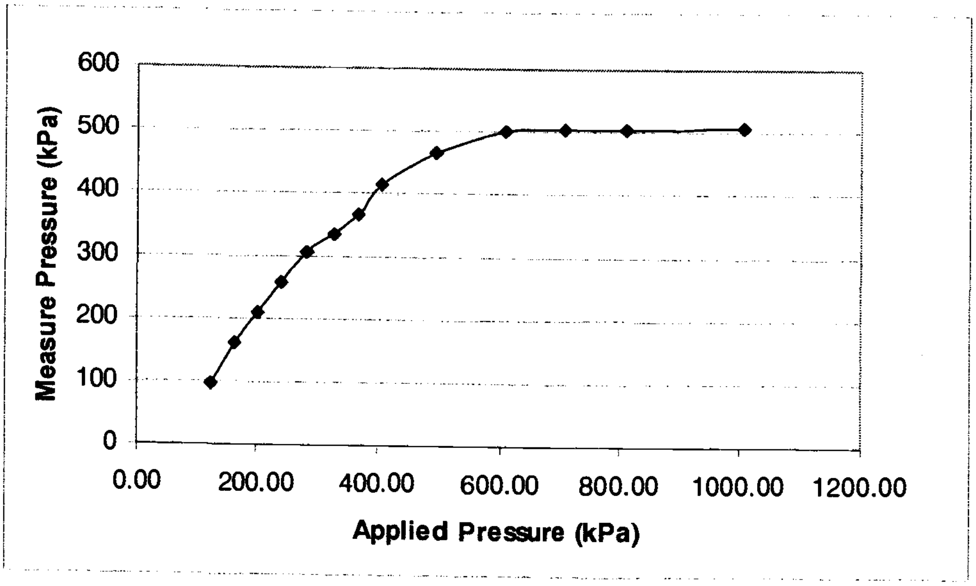


Figure 10. A comparison of the pressure sensor output to applied pressure for establishing the capacity of the measurement system.

Figure 11 depicts the hysteresis curve. The range of peak pressures applied to determine the amount of hysteresis in the system was from 100 to 405kPa. Evidence shows that hysteresis is going to occur. The biggest effect of hysteresis on the loading curve is less than 7%. Interesting to note, the loading curve is below the unloading curve on the graph. This is opposite of what is expected during hysteresis testing. Typically energy is lost during loading and unloading, however in this case the result implies that energy is gained.

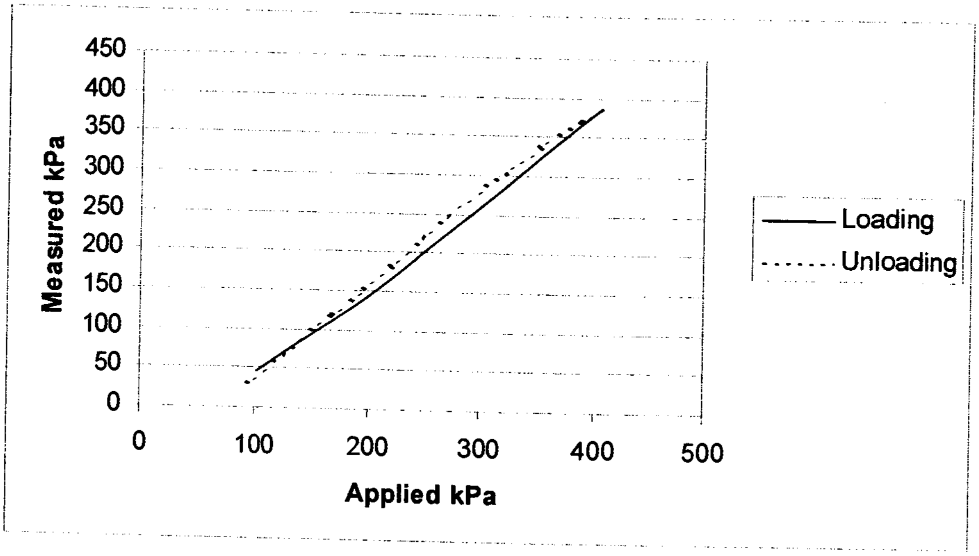


Figure 11. Hysteresis curve of the heel sensor

Frequency Response

Figure 12 depicts the response of the pressure sensor as a function of the applied signal G(f) at six different frequencies. The sensor data were collected at a rate of 200Hz using the heel sensor in the insole. The peak-to-peak amplitude of the applied signal is compared with the peak-to-peak amplitude of the corresponding sensor output. As the amplitude of the sensor output starts to decrease due to increased frequency, the response of the system starts to drop below G(f) = 1. At an applied pressure frequency of 17 Hz, there is a dramatic drop in the magnitude of the sensor output.

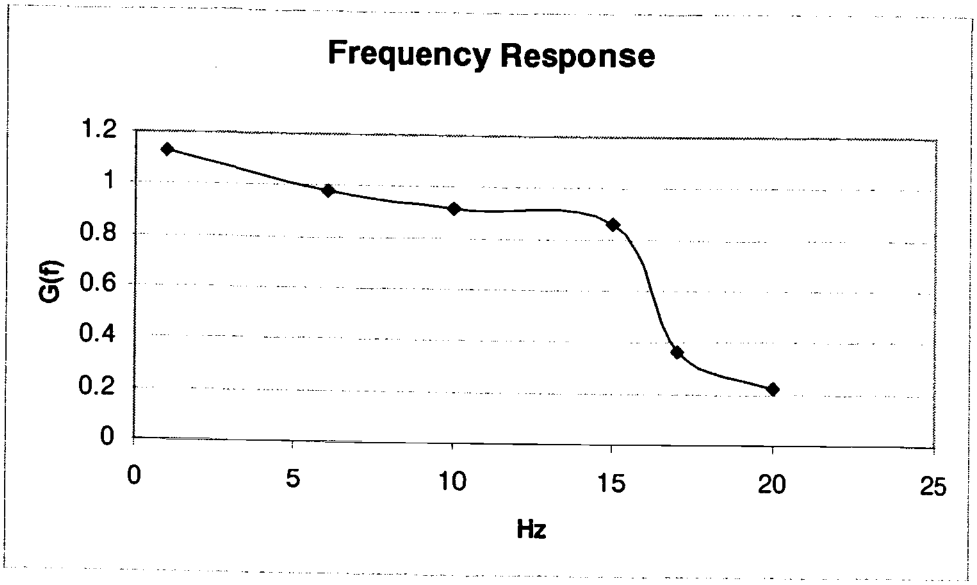


Figure 12. Frequency response: ratio G(f) of the average of peak pressures measured to the average of peak pressures applied.

Signal Response

A Tektronix oscilloscope was used to collect sensor data before amplification and acquisition (oscilloscope signal). These data were compared to the data collected after acquisition and computer processing (sensor signal). A sinusoidal load with an amplitude of 400kPa and a frequency of 3 Hz was applied to the heel sensor. Figure 13 depicts the comparison between the two signals. Because the voltage output decreases with increasing pressure, the valley of the signal on the graph represents the peak pressure. As mentioned previously, the clipped amplitude of the sensor signal exists due to the amount of power supplied to the amplifier in the electronic circuit. For the purposes of this project, the low pressure (or high voltage) values were not of interest. In order to get the full range of output, the amplifier must have more voltage supplied to the circuit.

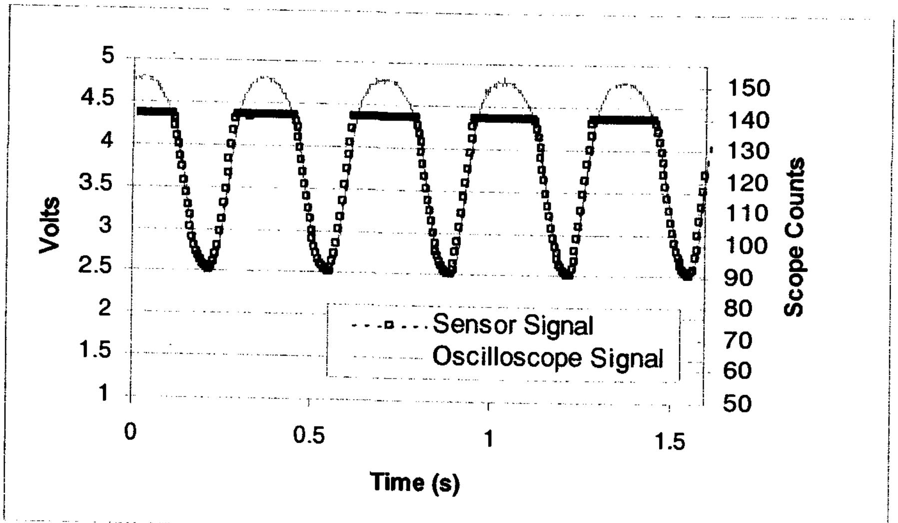


Figure 13. Sensor output signal vs. oscilloscope signal

Ability to Sense Average Pressure

Figure 14 depicts a comparison between the average amount of pressure measured by the heel sensor to the average amount of applied pressure between the three sizes of loading pellets. The applied loading area (A) is compared to the active measuring area on the sensor (S). The applied load is approximately 400kPa for all test trials. Sensor output was converted to pressure using the static calibration equation. Static calibration was conducted using the 8mm loading pellet, which is the same size as the sensing area on the pressure sensor.

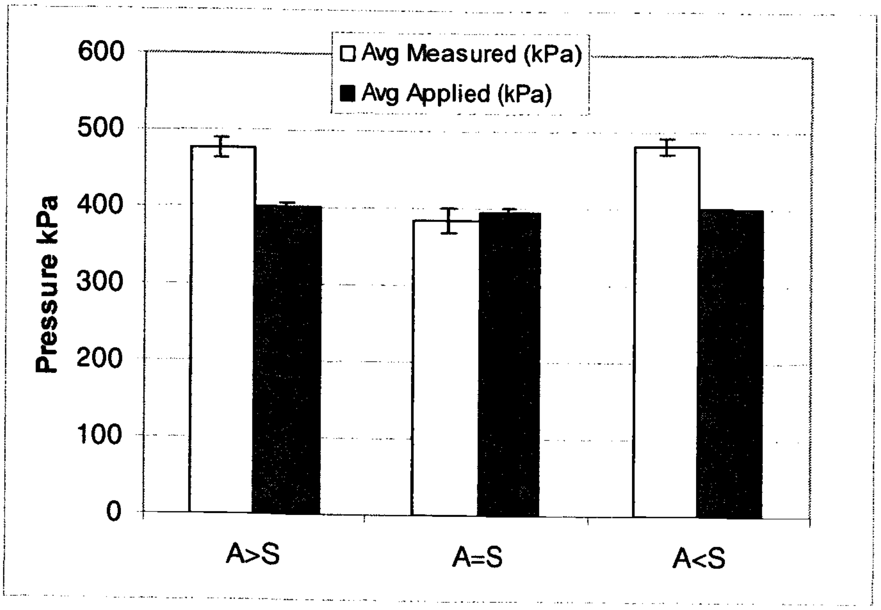


Figure 14. Comparison of pressure measured by sensors to pressure applied between 3 cylindrical loading pellets of different areas. For A>S, the area of the applied load is greater than the sensing area of the pressure sensor. For A=S, the area of the applied load and sensing area are similar. For A<S, the area of the applied load is less than the sensing area.

Reliability Testing Procedures

The means and standard deviations of the peak values at each 10-minute interval are presented in Table 3. A two-factor ANOVA test revealed that there were interaction effects between the time-intervals and loading ($p < 0.0001$). To determine if the effect of time was different between the applied and measured loading, a post-hoc Tukey test was performed. Results indicated that 5 different subsets exist between the time-intervals, the measured pressure, and the applied pressure. These subsets are displayed in Table 4.

Table 3. Mean and standard deviation (sd) of heel sensor output and applied pressure in kPa at 10-minute intervals

Interval (min)	Sensor (kPa)	Applied (kPa)
0-10	106.72 (1.51)	113.07 (3.87)
10-20	149.64 (5.47)	118.05 (10.12)
20-30	159.69 (1.43)	114.59 (5.49)
30-40	159.62 (8.60)	121.76 (9.34)
40-50	165.06 (3.97)	123.48 (7.81)
50-60	164.94 (7.19)	126.85 (4.94)

Table 4. Tukey test of applied pressure by Instron and pressure measured by sensor for each time interval

	Interval (min)	N	Subset for alpha = 0.05				
			1	2	3	4	5
Applied	0-10	8	113.07	113.07			
	10-20	8	118.05	118.05	118.05		
	20-30	8	114.59	114.59			
	30-40	8		121.76	121.76		
	40-50	8		123.48	123.47		
	50-60	8			126.85		
Measured	0-10	5	106.72				
	10-20	11				149.64	
	20-30	6				159.69	159.69
	30-40	7				159.62	159.62
	40-50	5					165.06
	50-60	9					164.94

The system yielded a change in the heel sensor output ($p<0.0001$) after a 10-kilometer run (Table 5). In addition, the sensor located at the 1st metatarsal head was also tested and yielded a change in output ($p<0.0001$) after the run (Table 6). For both sensors, the applied pressure did not change significantly. The average increase in temperature across all five sensors was 10°C from ambient. The heat lamp used to maintain an elevated temperature during testing was able to do this within an average of 1°C for all sensors.

Table 5. Results from heel sensor.

Mean peak pressure applied and mean peak sensor output in kPa before after a 10km run. Mean and standard deviation (sd) are presented at each temperature.

* significant differences before and after the run ($p < 0.0001$)

	Before Run	After Run
Applied	128.24 (8.10)	124.56 (4.46)
Sensor *	114.62 (2.41)	82.72 (2.89)

Table 6. Results from 1st metatarsal sensor.

Mean peak pressure applied and mean peak sensor output in kPa before after a 10km run. Mean and standard deviation (sd) are presented at each temperature.

* significant differences before and after the run ($p < 0.0001$)

	Before Run	After Run
Applied	123.30 (7.76)	124.48 (3.44)
Sensor *	118.17 (5.68)	90.26 (2.57)

The pressure measured from all 5 sensors in the first 3 walking steps from a standing position is displayed in Figure 15. The mass of the individual was 58kg. Each pressure sensor was calibrated independently, therefore the lowest measurable pressure value is not the same for all sensors. The highest pressures measured by the system were the first and second metatarsals, followed by the heel sensor. Because the sensors had not been through a warm-up period, the signals are not entirely stable and an increase in the output with each step is evident. This result is further evidence that the sensors have a history dependence that has affected the peak pressure measured.

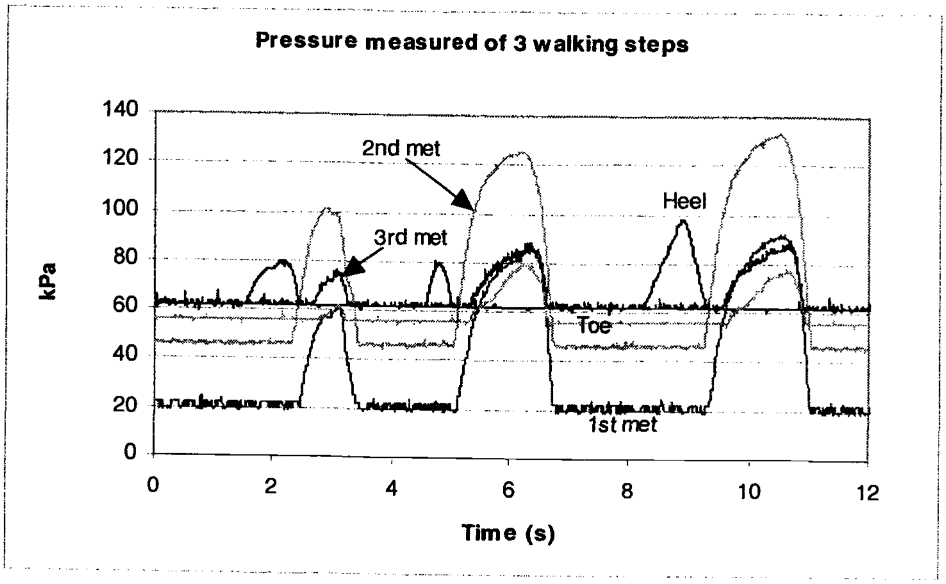


Figure 15. Pressure measured by 3 walking steps starting from standing position.

DISCUSSION

After evaluation of the test results, it is evident that the pressure sensors used for this system have a much lower capacity than what was specified by the vendor. The vendor reports a maximum pressure rating of approximately 780kPa, while the sensor is only able to measure up to 500kPa. While applying static loads to characterize the voltage output, drift in the data was evident. Figure 16 shows the voltage output of a sensor during static loading of approximately 360kPa. After one and a half minutes of loading there was a 3.4% change in the voltage output. Because of this response, there is a need to measure static loads at the same time point for each load change. This was done for the static calibration process, however it is unknown if this drift rate is constant for all load levels. The linear regression equation determined from static calibration was determined after a range of static loads had been applied to the sensor for at least one minute. For the given drift over time data, the change in voltage output after one minute was 2.1%. This amount of drift was not enough to explain the possible reasons for the significant difference in capacity. Perhaps future work could develop a true capacity and drift factor for each sensor.

Dynamic loading showed a 4% decrease in the average of peak pressures between the applied and measured load after 25 seconds of dynamic loading. This difference dropped to a 2% decrease after 2 minutes of dynamic loading. The pressure applied was at a rate of 6Hz, which is a faster stride rate than an average sprinter (Nummela, 1994). Looking at the frequency response of the system, the ratio of recorded pressure to applied pressure is very close to 1 for a 6Hz loading rate and 400kPa amplitude. The loading rate is most likely not a factor for the decrease in peak pressure. Considering there is a drift in the sensor output over a duration of applied pressure, it is possible that the time it takes for the sensor to fully recover with no loading is much longer than the no-load time available during dynamic loading.

Because the insole is going to be used to detect pressures between the

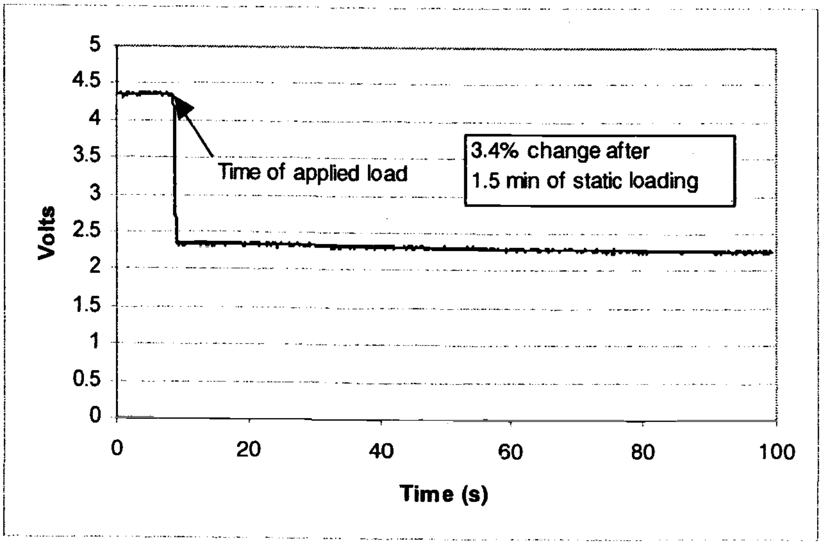


Figure 16. Sensor drift with static loading.

sensor and a human foot, understanding the sensor's ability to measure pressure with different areas of applied load was important. This was done by applying a constant pressure to a sensor across three load/area combinations. The sensor was able to measure pressure within 13kPa for the case of the applied loading (A) being equal to the sensing area of the transducer (S). For the cases of the applied loading being greater than and less than the sensing area, the sensor was capable of measuring within 75 to 82kPa, respectively. The sensor was calibrated using the pellet size that was equal to the sensing area (8mm). Future testing could examine different calibration testing methods and how they can impact the output of the sensor. Perhaps the material difference between the sensor and insole was enough to create an edge effect or perhaps there is a lack of consistency in the material used to fabricate the sensor that leads to these inaccuracies. Regardless, the high-pressure regions of a human foot are more than likely going to have a greater area than the sensing area of the transducer, therefore this discrepancy would have to be well defined for future use.

During reliability testing, the sensor was capable of consistent measurements after about 20 minutes of data collection. Interesting to note, in 2001, Maluf et al. recommended a 5-minute warm-up period during reliability testing in which they were using $200 Paromed pressure sensors in an insole. The details of how this warm-up was determined were not clear, however the system in this study shows a need for something similar.

The results of the elevated temperature test show a significant difference in the average of peak pressures pre and post 10 kilometer run. This difference may be associated with the increase in temperature or a drift factor within the sensor. For this study, the pre testing in the temperature test did not include a 20-minute warm-up. The post testing was performed immediately after the run. Perhaps the sensors were still in a compressed state and did not have the time to relax fully before more testing. Since the sensor specifications indicate a 10 to 40°C operating temperature and the testing increased the sensor temperature from approximately 20 to 30°C, it would be unlikely that the sensor was sensitive to this change.

The present study has developed a pressure measurement device based on low-cost. The performance of this system can be compared with current models that are commercially available by evaluating the duration of pressure application, calibration procedure, and applied pressure levels. Specifically, the F-scan and Pedar systems were tested for accuracy and precision by Hsiao et al., in 2002. The results of their testing indicated there was statistical significance in applied pressure, duration, calibration pressure, calibration procedure, and device age effects. Both of the systems showed greater accuracy when measurements were taken within a few seconds after pressure was applied. For the Pedar system, "data collected at 2 seconds yielded less error than data collected at 5 or 10 minutes" (Hsiao et al., 2002). Specifically, a time-dependent change of 3.6% existed after 5 minutes of applied static loading. After 10 minutes the change was 4.4%. For this study, a 3.4% change occurred after 1.5 minutes of static loading. The F-scan insole showed considerably higher system error, ranging from –26.6 to 33.9%, when the applied pressure was not comparable with the calibration pressure. The calibration procedure for this project was similar to how the F-scan and Pedar were calibrated for Hsiao's study. A known static pressure was sustained on the insole/sensor region and the corresponding output was recorded after a known time. However, in Hsiao's study, the pressure levels were sustained for 20 minutes versus the 1 to 2 minutes for this study. There is evidence that the calibration process is significant for this design because of the results for the sensing average pressure test. The system was more accurate when the area of the applied pressure was the same as the sensing area of the sensor.

Furthermore, the Pedar system showed a decrease in accuracy for applied pressures that were less than 35kPa. The F-scan system could reliably measure 50kPa and greater provided the calibration pressure and applied pressure were comparable. Although the accuracy at different pressure levels was not studied in this project, it is worthy to note that this device was unable to measure pressures less than 25kPa. Last, the Pedar insoles showed a significant decrease in accuracy and precision from a new insole to a one-year-old insole. This indicates that the Pedar insole must be replaced after a period of use. Because the cost of a new Pedar system is over $10,000, a low-cost alternative is even more desirable.

For this design and characterization process, several limitations are worthy of mention for future development. Only one in-sole pressure measurement system was developed and tested in this study, which was appropriate for a proof of concept system. For most test procedures, only one sensor was tested. In order to characterize the entire measurement system, each sensor must be considered. Second, pressure sensors are sealed with a rubber coating and the effects of humidity are assumed to be negligible. Prolonged exposure to moisture and pressure could alter the sensor's values or cause material failure. It would be worthy of note that through all the tests performed, especially for the heel sensor, not one failure in the electronic connections or sensor material occurred. Finally, although studies exist that indicate the high-pressure anatomical locations of the foot, the pressure sensors were only roughly placed in these areas. The actual pressure values that would be recorded may not reflect the high-pressure region of the anatomical landmark selected. Future work could include customized placement of discrete sensors within the insole in order to facilitate a better placement, or the functionality of the in-sole could be described as only a system for sensing alterations in endurance sports or pre and post surgical procedures.

The parameter evaluated for most of the tests was the average of peak pressures during cyclic loading. The software developed to collect and display the raw data was not programmed to provide subsequent calculations to report this parameter. Having the ability to retrieve this information immediately would significantly reduce the amount of time spent in analysis. In addition, it would be helpful to have other information such as loading rate (stride rate), foot contact time, non-contact time, maximum peak pressure, and average pressure.

CONCLUSION

An affordable, easy to use, plantar pressure measurement system has been developed that can provide extended measurement in an environment that exists in the shoe of a participant. With careful analysis of the data, information about the stride rate, number of steps, and activity time could be extracted. Because of the small number of sensors used, a high frequency sampling rate may be used to capture high-speed activities. This system has shown to be highly responsive to pressure changes and further development would improve the reliability and accuracy of this design. In addition, the application of portable power and memory storage would enable this system to be completely contained in the insole of a shoe.

BIBLIOGRAPHY

Abu-Faraj, Z. O., Harris, G. F., Abler, J.H., Wertsch, J.J. (1997). A Holter-type, microprocessor-based, rehabilitation instrument for acquisition and storage of plantar pressure data. Journal of Rehabilitation Research and Development, 34(2), 187-194.

Elliot, B.C., Ackland, T. (1981). Biomechanical effects of fatigue on 10,000 meter running technique. Research Quarterly for Exercise and Sport, 52(2), 160-166.

Elliot, B.C., Roberts, A.D. (1980). A biomechanical evaluation of the role of fatigue in middle-distance running. Canadian Journal of Applied Sports Science, 5(4), 203-207.

Frederick, E.C., Hagy, J.L. (1986). Factors affecting peak vertical ground reaction forces in running. International Journal of Sport Biomechanics, 2, 41-49.

Hsiao, H., Guan, J., Weatherly, M. (2002). Accuracy and precision of two in-shoe pressure measurement systems. Ergonomics, 45(8), 537-555.

Kirtley, C. (2003). Instrumented Insole. United States Patent Application Publication No. US 2003/0009308 A.

Kirtley, C. (2001). An instrumented insole for kinematic and kinetic gait measurements, Proc. of the 5th Symposium of Footwear Biomechanics, 52-53.

Maluf, K.S., Morley, R.E., Richter, E.J., Klaesner, J.W., Mueller, M.J. (2001). Monitoring in-shoe planter pressure, temperature, and humidity: reliability and validity of measure from a portable device. Archives of Physical Medicine and Rehabilitation 82, 1119-1127.

Morley, R.E., Richter, E.J., Klaesner, J.W., Maluf, K. S., Mueller, M.J. (2001). In-shoe multisensory data acquisition system. IEEE Transactions of Biomedical Engineering, 48(7), 815-820.

Nummela, A., Rusko, H., Mero, A. (1994). EMG activities and ground reaction forces during fatigued and nonfatigued sprinting. Medicine and Science in Sports and Exercise, 26(5), 605-609.

Orlin, M.N., McPoil, T.G. (2000). Plantar Pressure Assessment. Physical Therapy, 80(4), 399-409.

Paradiso, J., Hu, E., Hsiao, K. (1998). Instrumented footwear for interactive dance. Presented at the XII Colloquium on Musical Informatics, Gorizia, Italy, September 24-26.

Pataky, Z., Faravel, L., Silva, J.D., Assal, J. P. (2000). A new ambulatory foot pressure device for patients with sensory impairment. A system for continuous measurement of plantar pressure and a feed-back alarm. Journal of Biomechanics, 33, 1135-1138.

Schaff, P.S. (1993). An overview of foot pressure measurement systems. Clinics in Podiatric Medicine and Surgery, 10(3), 403-415.

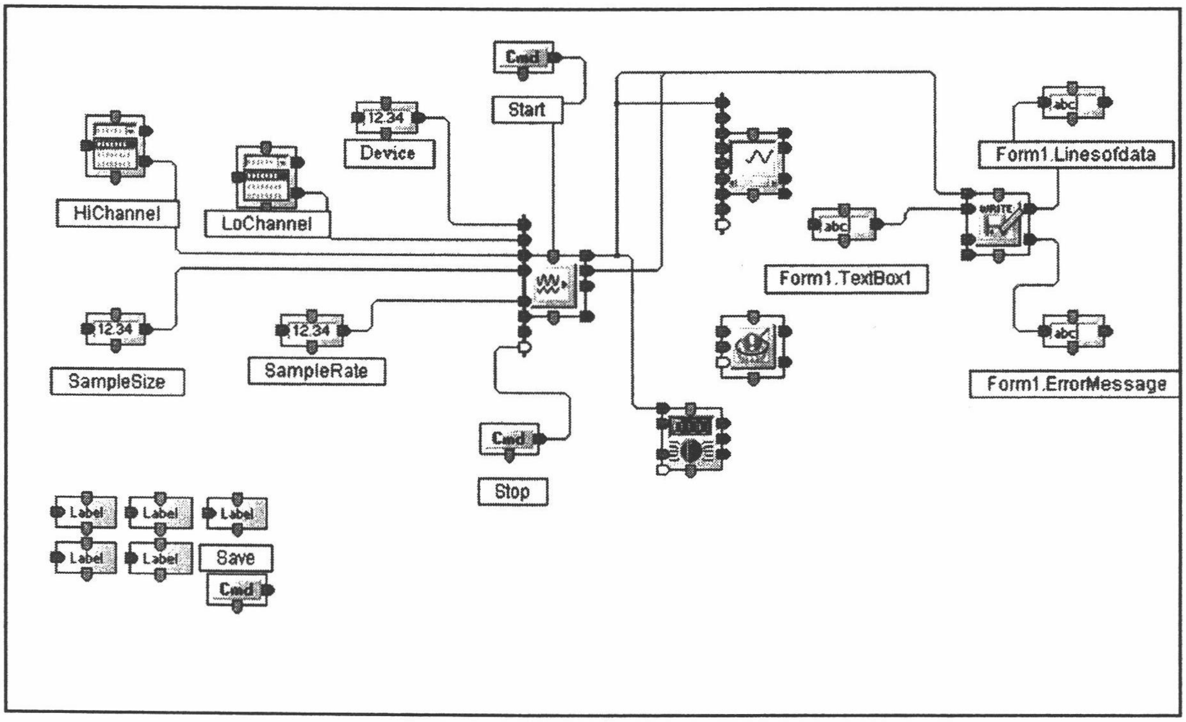
Willson, J.D., Kernozek, T. W. (1999). Plantar loading and cadence alterations with fatigue. Medicine & Science in Sports & Exercise, 31(12), 1828-1833.

Winters, D.A. (1990). Biomechanics and Motor Control of Human Movement (2nd ed.). New York: John Wiley & Sons, 36-40.

Zhu, H., Wertsch, J.J., Harris, G.F., Alba, H.M., Price, M.B. (1993). Sensate and insensate in-shoe plantar pressures. Archive of Physical Medicine in Rehabilitation, 74, 1362-1368.

APPENDICES

APPENDIX A: Softwire Diagram



APPENDIX B: Test Plans

Frequency Response

Purpose: To determine the frequency response of the pressure measurement insole. The frequency response is the ratio between the magnitude of the applied signal and the magnitude of the corresponding sensor output as a function of the applied signal. At high frequencies, the measurement system may attenuate the signal causing a delay in time and affecting the peak pressure measurements.

Test Procedures:

1. Place insole on rigid surface between EnduraTEC loading mounts
2. Connect insole to data acquisition (DAQ) and DAQ to notebook
3. Use the 0.312″ (8mm) loading pellet for this test (to create 406kPa load)
4. Set sample frequency for sensor output and load input at 200Hz
5. Using the heel sensor, apply the sinusoidal wave at the amplitude and frequency indicated below.

Amplitude (N)	Frequency (Hz)
20	1
20	3
20	6
20	10
20	15
20	17
20	20

6. Collect sensor output and applied load input data for 3 minutes or until the signal becomes consistent.
7. Repeat the process for the remaining amplitude/frequency pairs.

Equipment:

- EnduraTEC ELF 3200
- Measurement Computing PMD-1208LS Data Acquisition with custom circuit board for signal amplification of pressure sensors
- Custom insole with 5 CUI pressure sensors mounted to high load areas of insole
- Notebook computer for data collection and processing in Visual basic

Hysteresis

Purpose: For this system, the hysteresis is quantified as the greatest difference between the voltage output at a given pressure during loading and unloading. The purpose of this test was to determine this difference.

Test Procedures:

1. Place insole on rigid surface between EnduraTEC loading mounts
2. Connect insole to data acquisition (DAQ) and DAQ to notebook via USB cable
3. Set data acquisition on EnduraTEC to record the load during testing
4. Ensure the loading pellet is in place and over the center of the pressure sensor.

a. Use loading pellet D = 8mm

5. Start loading one sensor at a time using the test parameters listed above. At each load step wait for the sensor output to stabilize before recording the voltage.
6. Step the load back down to zero in the same number of steps.

Start at step 1 and step up to the maximum load in the following order –

	Load (N)	Pressure (kPa)
Step 1	5	101.5
Step 2	10	203
Step 3	15	304.5
Step 4	20	406

Express the results as a percent of the voltage output during peak loading.

Equipment:

- EnduraTEC ELF 3200
- Measurement Computing PMD-1208LS Data Acquisition with custom circuit board for signal amplification of pressure sensors
- Custom insole with 5 CUI pressure sensors mounted to high load areas of insole
- Notebook computer for data collection and processing in Visual basic

Ability to Sense Average Pressure

Purpose: The material properties of the insole and pressure sensor are different, therefore it is important to understand if the average pressure applied to the sensor is the same as the pressure measured by the sensor. Three combinations of force and area will be applied to the sensor while maintaining the same pressure. In each case, the sensor should output the same voltage.

Test Parameters:

1. Place insole on rigid surface between EnduraTEC loading mounts
2. Connect insole to data acquisition (DAQ) and DAQ to notebook via USB cable
3. Program EnduraTEC to apply the loads listed below
4. Start with the heel sensor and apply the load indicated for each loading pellet size of different diameters. Collect sensor output data until the reading is stable. Repeat the process for the next 2 pellet sizes.

Pressure = 400kPa

Diameter m (in)	Force (N)
.0127 (.5)	51
.00792 (.312)	19.7
.0063 (.25)	19.7

Display the sensor output for each Force/Area combination in kPa

Equipment:

- EnduraTEC ELF 3200
- Measurement Computing PMD-1208LS Data Acquisition with custom circuit board for signal amplification of pressure sensors
- Custom insole with 5 CUI pressure sensors mounted to high load areas of insole
- Notebook computer for data collection and processing in Visual basic (VB)

Performance over time

Purpose: To determine the effects of one hour of cyclic loading on the insole pressure sensors.

Test Procedures:

1. Place insole on the Instron compression plate and secure with tape.
2. Connect insole to data acquisition (DAQ) and DAQ to notebook via USB cable
3. Program Instron to cyclic load between 0 to 30N at a rate of 30N/s (~0.5Hz)
4. Load each sensor one at a time while collecting sensor data every 10 minutes for 15 seconds.
5. Total Test Time: 60 minutes (50 min for 1, 2, & 3rd met)
6. Repeat for other sensors.

Equipment:

- Instron 5567 ISO 9001 Registered
- Measurement Computing PMD-1208LS Data Acquisition with custom circuit board for signal amplification of pressure sensors
- Custom insole with 5 CUI pressure sensors mounted to high load areas of insole
- Notebook computer for data collection and processing in Visual basic (VB)

Temperature Effects

Purpose: To determine the effects of elevated temperature and humidity on the insole pressure sensors.

Test Procedures:

1. Place insole on the Instron compression plate and secure with tape.
2. Connect insole to data acquisition (DAQ) and DAQ to notebook via USB cable
3. Program Instron to cyclic load between 0 to 30N at a rate of 30N/s (~0.5Hz)
4. Load each sensor one at a time for 30 seconds while collecting data with VB program.
5. Go on 6 mile run.
6. Immediately following run (which will end in the lab), removed the insole from shoe and measure the temperature of each sensor.
7. Place insole on the Instron mounting surface and ensure heat lamp is in place.
8. Measure the sensor temperature before testing.
9. Repeat #4.

Equipment:

- Instron 5567 ISO 9001 Registered, Canton MA
- Measurement Computing PMD-1208LS Data Acquisition with custom circuit board for signal amplification of pressure sensors
- Custom insole with 5 CUI pressure sensors mounted to high load areas of insole
- Notebook computer for data collection and processing in Visual basic (VB)
- Thermocouples for measuring sensor temp over time with handheld instrument readout