34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Sensor Architectural Tradeoff for Diabetic Foot Ulcer Monitoring

Sarah Ostadabbas, Adnan Saeed, Mehrdad Nourani
Department of Electrical and Computer Engineering
University of Texas at Dallas, Richardson, TX 75080
{sarahostad, axs055200, nourani}@utdallas.edu

Matthew Pompeo, M.D.
Presbyterian Wound Care Clinic
Dallas, TX 75231
healerone@aol.com

***Abstract*—The diabetic foot complications constitute a tremendous challenge for patients, caregivers, and the healthcare system. Studies show up to 25% of diabetic individuals will develop a foot ulcer during their lifetime and many of these patients eventually must undergo amputation as a result of infection due to untreated foot ulcers. With current technology, in-shoe monitoring systems can be implemented to continuously monitor at-risk ulceration sites based on known indicators such as peak pressure. The important parameters in designing a pressure-sensing insole include the number, location and size of sensors. In this paper, we aim at showing the criticality of sensor architectural tradeoff in developing the *in-shoe* plantar pressure monitoring systems. We evaluate this tradeoff by using our custom-made platform for data collection during normal walking.**

I. Introduction

Studies show about 5.1% of the United States population suffer from diabetes [1]. Up to 25% of diabetic individuals will develop a foot ulcer during their lifetime and many of these patients eventually must undergo amputations as a result of infection due to untreated foot ulcer [2]. Any reduction in the rate of diabetic foot complications would be significant to healthcare providers, and more importantly, would improve the quality of life for many individuals.

Diabetic patients have problems with their feet mainly because of poor blood flow, poor sensation (diabetic neuropathy), decreased wound healing rate, and trouble fighting off infection [3]. With diabetes, even a wound as small as a blister, e.g. due to a tight shoe, can cause considerable damage. In such patients, the injuries heal slowly because of decreased blood flow. When a wound is not healing, it's at risk for infection. Moreover, diabetic patients with neuropathic feet lack the sensory feedback that indicates the need to change gait patterns, rest, or remove a shoe to allow the traumatized foot to recover [4].

The primary recommendations for preventing diabetic foot ulcers are daily foot inspections, temperature monitoring, and orthotic shoes [5]. Educating patients to perform daily self-examination and properly care for their feet is inexpensive and universally recommended. A promising variant of this is daily measurement of foot temperature. Finding elevated temperature in the foot is a significant early indicator of ulceration. Proper diabetic footwear has been shown to be effective in reducing the rate of neuropathic foot ulceration [6]. Despite the proven effectiveness of appropriate diabetic footwear, patient compliance is a major issue. Surveys show patients are not wearing these shoes regularly due to some practical and personal reasons, including atheistic, comfort, durability, and cost [7].

All preventive techniques require patients to perform certain tasks regularly (foot care, temperature measurement, or wearing shoes). The biggest challenge, then, is patient compliance. An electronic in-shoe monitoring system would be able to track compliance continuously and give the results to the care staff. By taking advantage of current technology, these devices can be placed as an insole into normal shoes. Also, considering aesthetic in their designs can lead to understand what design factors can increase patients compliance.

Several systems for measuring plantar pressure in the foot are commercially available, such as Pedar [8] and F-Scan [9] systems. These systems are extremely expensive and aim at athletic activities/exercises and cost tens of thousands of dollars per unit.

For such a system to be affordable to patients, it would need to be at a much better price. This price point can be reached with some compromising: primarily the number of sensors in the shoe would be very limited. Several studies have examined such systems, which consist of several resistive force sensors laid out on an insole [10, 11]. These studies looked at sensor placement and proved that such a system was possible, although both systems required a computing device/gateway attached to the waist.

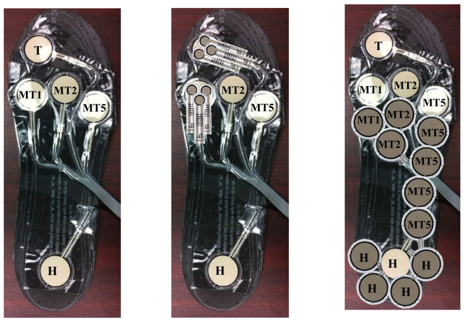
Our system is similarly a lab prototype attachable to the shoe. The main contribution of our work is showing the importance of architectural tradeoff (the number and location of sensors and the sensor size) to design an individualized pressure-sensing insole. We validate our system with an 11-person walking trial and show that our results are consistent with other studies. We also compare the use of 1 inch and 3.75 inch diameter sensors and examine the tradeoffs for each choice.

II. Data Acquisition Platform

To measure the pressure on different plantar areas of human feet we sandwiched FlexiForce force sensors [9] between two inexpensive shoe insoles. Two sizes of sensors were used: a 1 inch diameter force sensor and a 0.375 inch diameter sensor. Our custom-made insole with two size sensors are shown in

978-1-4577-1787-1/12/$26.00 ©2012 IEEE

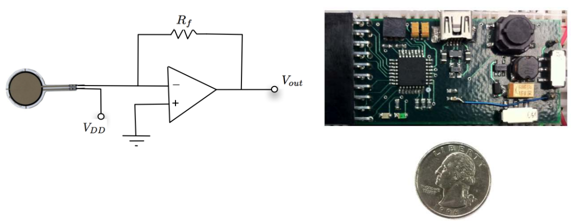
Fig. 1a, Fig. 1b and Fig. 1c that have different number of sensors. Sensor placement could easily be changed based on subject and experiment.



(a) 5 large (b) 6 small and 3 large (c) 16 large

Fig. 1. Custom-made insole with different number of force sensors

For these experiments, we are using a prototype sensor board that uses the TekScan-recommended circuitry for linearizing force data [9], shown in Fig. 2a. To achieve the higher range of force measurement, as it was suggested by the sensor datasheet, we reduced the drive voltage to $V_{DD} = 2.5\,V$, and the resistance value of the feedback to $R_f = 20\,K\Omega$.



(a) Recommended drive circuit [9] (b) Custom-designed electronic board

Fig. 2. Typical sensor platform

The data was collected with a custom data acquisition platform based on the MSP430 microprocessor from Texas Instruments. An on-board 1GB micro SD card stored the data for later retrieval. The sensor data was sampled at $250Hz$ from up to eight force sensors. Our custom designed data acquisition board is shown in Fig. 2b.

III. Architectural Tradeoff

From a medical standpoint, it is the pressure on various parts of the foot responsible for forming foot ulcers. Several key areas have been identified where ulcers are most likely to develop [12]. Continuously monitoring sensors placed in those areas will allow us to predict at-risk areas and ulceration onset sites based on known indicators such as peak pressure.

The important parameters in designing a pressure-sensing insole include the number and location of sensors and the sensor size. The question of sensor size has not been formally addressed in the context of pressure ulcers, but has many interesting implications. The most common pressure sensors are actually force sensors, which can be used to compute average pressure over the surface of the sensor. Larger sensors cover more area, but will underestimate the peak pressure. Smaller sensors are more vulnerable to misplacement, but have potential to measure pressure more accurately at certain spots. These issues will be covered in details in Section III-B.

A. Sensor Placement

A study that was conducted on 87 patients, with 103 existing foot ulcers, showed that ulcers were located mostly under the metatarsal heads (56.3%), under the toes (32.1%), and at the heel (1.9%) [12]. It is also known that the majority of diabetic foot ulcers are developed on the plantar surface of the foot at sites of high pressure [13].

Based on these observation, we decided to use five sensors placed in the toe area (T), metatarsal heads (MT1, MT2, MT3/5) and heel (H), as shown in Fig. 3a. Since sensors should be placed in the sites of the highest pressure, the exact position was determined per-patient using a footprint, as recommended in [10]. The exact method is explained in Section IV.

Even though those are the areas most likely forming pressure ulcers, the exact location of the pressure sensor is not clear. Sixteen 1-inch sensors were placed around the foot as shown in Fig. 3b, and two subjects were asked to stand still. The average force readings are shown in Fig. 3. The total weight picked up by all sensors is almost 70% of the subject's weight. The peak force sites in each region are shown with lighter color in the figure. The two people show different distribution of forces, and clearly the peak pressure is not limited to a single area. This shows the importance of placing sensors based on the subject's peak pressure in each zone.

B. Sensor Size

The proper size of sensor that adequately cover at-risk area, and simultaneously not being large to underestimate peak pressure, has not been addressed in the literature. If the total force measured by the sensors is divided by the sensor area, the average pressure across the sensor is obtained. While some regions, such as the heel, show semi-uniform pressure over large areas, other regions show strong peaks [14]. The tradeoff

(a) High risk regions (b) Force readings (lbs) from two different subjects

Fig. 3. Medically-important plantar areas and force distribution on custom-made insole with 16 sensors

is that smaller sensors underestimate the total force and may not be placed well to receive the peak pressure. The larger sensors, on the other hand, are more likely to contain the peak pressure, but the reading may be a significant under-estimation of the peak pressure.

In order to compare the force and pressure distribution based on sensor size, we analyze the sensor readings from two different insoles. One with large sensors (Fig. 1a) and the other with small sensors covering the area of large sensors (Fig. 1b). For the MT1 (first metatarsal head) and Toe regions, three small sensors were placed to cover the same area as a single large sensor, determined by $\mathrm{MT1}_1$, $\mathrm{MT1}_2$, $\mathrm{MT1}_3$, and Toe_1, Toe_2, Toe_3, respectively. The total force for the small sensors can be obtained by adding all the forces in a single region, while the peak pressure should be obtained by picking the maximum pressure from all sensors.

The average peak force and peak pressure (force divided by area) during normal walking from a $90\,\mathrm{kg}$ male subject for the small sensors in shown in Table I. The comparison between small and large is shown in Table II. As expected, the small sensors under-measure the force, while the large sensors underestimate the peak pressure. For the first metatarsal, the pressure difference was small, but for the toe it was quite large. This illustrates the need to develop better methods to improve this estimation.

Examining this problem from a medical standpoint, average wound size is reported to be from $2.8\,\mathrm{cm}^2$ [15] to $5.9\,\mathrm{cm}^2$ [16]. Assuming a circular shape, this corresponds to $0.72\,\mathrm{inch}$ to $1.08\,\mathrm{inch}$ diameter wounds. This suggests that a larger sensor would be needed to cover the area that can develop a wound.

The formal optimization/tradeoff for architectural sensor design is beyond the scope of this paper. However, based on our observations and experiments, the following guidelines are suggested:

- At-risk plantar regions are subjective. In the calibration phase, higher resolution (more sensors) can be used to locate the exact sites of the highest pressure for each subject in order to adjust the sensor placement.
- For the plantar regions with larger area, using a large sensor size that could cover the area is the best choice.
- For small plantar regions, using large size sensor leads to notable pressure underestimation, while smaller size sensors can measure peak pressures more accurately.

TABLE I
SMALL SENSOR FORCE/PRESSURE READINGS

Sensor Location	Peak Force (N)	Peak Pressure (kPa)
$\mathrm{MT1}_1$	15.8	221.6
$\mathrm{MT1}_2$	17.6	246.4
$\mathrm{MT1}_3$	11.1	154.5
Toe_1	28.2	396.3
Toe_2	43.3	608.0
Toe_3	5.7	79.7

TABLE II
COMPARING SMALL VS. LARGE SIZE SENSORS

Sensor Size	Peak Force (N)	Under Measure (%)	Peak Pressure (kPa)	Under Estimate (%)
MT1-small	44.5	57.2%	246.4	–
MT1-large	103.9	–	205.2	16.7%
Toe-small	77.2	24.0%	608.0	–
Toe-large	101.6	–	200.7	67.0%

IV. EXPERIMENTAL RESULTS

Data collection was performed on a group of eleven subjects, two females, and nine males in age range from 18 to 51 years old. Three sizes of insoles were used for different subjects: female shoe size 8 and male shoe sizes 9 and 10 (all sizes are based on U.S. conventions). The subjects inserted the insole in their shoes. Each insole has large size Flexiforce sensors taped on five medically-important plantar locations as can be seen in Fig. 1a. The exact sensor placement for each subject was done by using a weight-bearing imprint of the subject's feet. These foot imprint also show the contact area and arch shape of each foot.

Subjects were asked to walk normally in a hallway for $80\,\mathrm{m}$ non-stop. Steps at the ends of the walkway in each corner were excluded to eliminate any altered gait patterns during turning. They were also required to stand still for about $30\,\mathrm{sec}$ and stand on their right legs and keep stable for about $10\,\mathrm{sec}$ at the end of their walking experiments.

A. Analysis Metrics

Most medical literature on foot ulcers based their analysis on two values calculated per gait cycle: peak pressure, and the pressure-time integral [17]. Kosiak demonstrated that for pressure ulcers, there is an inverse relationship between pressure and time [18]. Since then, it is well accepted that the development of ulceration is not only related to the amount of applied pressure but also the duration of time the pressure is applied . The pressure-time integral is a combined metric that examines both the peak pressures and the time duration.

B. Tradeoff Results

In order to locate the start/end of a gait cycle, the maximum pressure in all intervals where heel pressure exceeds a fixed threshold is used to find the start of the gait cycle. Two extracted gait cycles from one of the subjects with different insoles are pictured in Fig. 4. The gait starts when the heel contacts the ground, then while the heel is lifted, the forefoot lands. The total pressure experienced by the foot during forefoot contact is maximum since for a very short period of time, all body weight is applied on one forefoot. Comparing Fig. 4a and Fig. 4b clearly shows the peak pressure underestimation by using large sensors. For this particular subject, this means $550\,\mathrm{kPa}$ maximum total pressure in Fig. 4a (underestimate) versus $1700\,\mathrm{kPa}$ (accurate) in Fig. 4b.

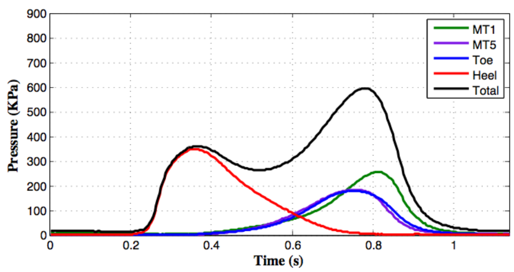
The combined results of all 11 subjects are illustrated in Table III. For each metric, the mean value, standard deviation (S.D.) and coefficient of variance (C.V.) were calculated

TABLE III

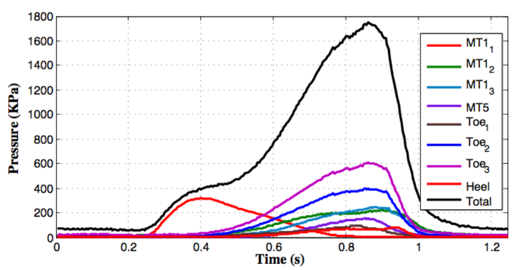
FOOT PLANTAR FORCE AND PRESSURE DISTRIBUTION OF ALL SUBJECTS DURING NORMAL WALKING

	Peak Force (N)			Force.Time Integral (N.sec)			Peak Pressure (kPa)			Pressure.Time Integral (kPa.sec)		
Sensor Location	Mean	S.D.	C.V.	Mean	S.D.	C.V.	Mean	S.D.	C.V.	Mean	S.D.	C.V.
MT1	48.0	23.4	2.1	14.7	7.0	2.1	94.7	46.2	2.1	29.0	13.9	2.1
MT2	57.7	26.9	2.1	14.9	7.1	2.1	114.0	53.1	2.1	29.3	14.0	2.1
MT5	34.2	16.8	2.0	9.3	4.9	1.9	67.6	33.1	2.0	18.4	9.6	1.9
Toe	62.6	17.7	3.5	15.3	4.7	3.2	123.5	34.9	3.5	30.3	9.3	3.2
Heel	93.8	31.3	3.0	25.1	9.3	2.7	185.1	61.8	3.0	49.5	18.4	2.7

among all of the subjects. The average gait times were in the range of 110 msec to 126 msec, and the number of steps used for analysis were between 40 to 100. Table III shows that our pressure measurements (peak values between 67.6 and 185.1 kPa) are consistent with other studies in medical community (e.g. peak pressure in the range of 40 kPa to 179 kPa was reported in [11]).



(a) 4 large sensors



(b) 6 small and 2 large sensors

Fig. 4. Sensor readings in a gait cycle from two insoles

V. CONCLUSION AND FUTURE WORK

Foot complications are common in diabetic patients and are considered one of the most expensive complications to treat. The current method to prevent diabetic foot ulcers is doctor prescribed shoes and orthotic inserts to reduce the risk of ulceration by decreasing high plantar pressure. Unfortunately, there is no precise and practical way to determine the effect of prescribed shoes and shoe modifications on diabetic feet without performing in-shoe pressure monitoring. In this paper, we showed the importance of sensor's architectural parameters in designing a pressure-sensing insole including the number, location and size of sensors. Our experiments on sensor placement quantified the importance of placing sensors based on the subject's peak pressure in each medically-important plantar region. Our experimental results in size tradeoff also showed that smaller sensors underestimate the total force and may not be placed well to receive the peak pressure. The larger sensors, on the other hand, are more likely to contain the peak pressure, but the reading may be a significant under-estimation of the peak pressure. This system was a prototype for our next generation board, which will support up to 32 simultaneous inputs and have an integrated Bluetooth module with built-in force linearization circuitry.

REFERENCES

[1] American Diabetes Association, *http://www.diabetes.org/*, 2011.

[2] N. Singh, D. Armstrong, and B. Lipsky, "Preventing foot ulcers in patients with diabetes," *JAMA: the journal of the American Medical Association*, vol. 293, no. 2, pp. 217–228, 2005.

[3] R. Macfarlane and W. Jeffcoate, "Factors contributing to the presentation of diabetic foot ulcers," *Diabetic medicine*, vol. 14, no. 10, pp. 867–870, 1997.

[4] A. Veves, H. Murray, M. Young, and A. Boulton, "The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study," *Diabetologia*, vol. 35, no. 7, pp. 660–663, 1992.

[5] D. Lott, M. Hastings, P. Commean, K. Smith, and M. Mueller, "Effect of footwear and orthotic devices on stress reduction and soft tissue strain of the neuropathic foot," *Clinical biomechanics*, vol. 22, no. 3, pp. 352–359, 2007.

[6] M. Mueller, "Therapeutic footwear helps protect the diabetic foot," *Journal of the American Podiatric Medical Association*, vol. 87, no. 8, pp. 360–364, 1997.

[7] E. Knowles and A. Boulton, "Do people with diabetes wear their prescribed footwear?" *Diabetic medicine*, vol. 13, no. 12, pp. 1064–1068, 1996.

[8] NovelUSA, "The Pedar System," *http://www.novelusa.com/*, 2011.

[9] Tekscan, "Pressure mapping, force measurement, and tactile sensors," *http://www.tekscan.com/*, 2011.

[10] Z. Abu-Faraj, G. Harris, J. Abler, and J. Wertsch, "A holter-type, microprocessor-based, rehabilitation instrument for acquisition and storage of plantar pressure data," *Journal of rehabilitation research and development*, vol. 34, pp. 187–194, 1997.

[11] Z. Pataky, L. Faravel, J. Da Silva, and J. Assal, "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*, vol. 33, no. 9, pp. 1135–1138, 2000.

[12] L. Lavery, E. Peters, and D. Armstrong, "What are the most effective interventions in preventing diabetic foot ulcers?" *International wound journal*, vol. 5, no. 3, pp. 425–433, 2008.

[13] E. Katoulis, A. Boulton, and S. Raptis, "The role of diabetic neuropathy and high plantar pressures in the pathogenesis of foot ulceration," *Hormone and metabolic research*, vol. 28, no. 4, pp. 159–164, 1996.

[14] S. Albert and L. Christensen, "Diabetic foot pressure studies," *The Lower Extremity*, vol. 1, no. 1, pp. 21–27, 1994.

[15] P. Sheehan, P. Jones, A. Caselli, J. Giurini, and A. Veves, "Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial," *Diabetes care*, vol. 26, no. 6, pp. 1879–1882, 2003.

[16] D. Margolis, L. Allen-Taylor, O. Hoffstad, and J. Berlin, "Diabetic neuropathic foot ulcers," *Diabetes Care*, vol. 25, no. 10, pp. 1835–1839, 2002.

[17] R. Stess, S. Jensen, and R. Mirmiran, "The role of dynamic plantar pressures in diabetic foot ulcers," *Diabetes Care*, vol. 20, no. 5, pp. 855–858, 1997.

[18] M. Kosiak *et al.*, "Etiology and pathology of ischemic ulcers," *Archives of Physical Medicine and Rehabilitation*, vol. 40, no. 2, pp. 62–69, 1959.