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Diabetic Patients Foot Care Using Smart Materials to Prevent Ulcerations/Amputations

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Abstract: A major cause of illness and disability in diabetic patients are complications affecting the lower limbs, in particular, the feet. It is believed that elevated plantar pressure plays a major role in foot problems in diabetic patients. It is proposed that high foot pressure concentrations may be avoided by developing a novel shoe insert based on the mechanics of smart materials. This paper describes the conceptual design of an automatic system that continuously monitors and controls the pressure levels in diabetic patients' feet. The scheme is based on the constant measurement of pressure levels and an active change in the shape of the shoe insert so as to decrease high-pressure levels. Sensing and actuation is done by the use of smart materials powered by a battery pack in the insert. All of the circuitry is envisioned to be on a single VLSI chip embedded in the shoe insert, hence making the shoe insert completely autonomous. Genetic algorithms will be used to select the optimal shapes and hence provide the smart materials with the correct voltage inputs so as to alter the shape of the insert. The greatest strength of the system is that it will be an active real-time system that will adapt to changes in the locations of high stress points, hence being superior to currently used passive shoe inserts and other forms of diabetic foot care. The focus of this paper is to show the preliminary use of genetic algorithms to quickly select an optimal shape that can be created by discretely placed actuators so as to reduce the high levels of plantar pressures.

Introduction

There are about 16 million people in the U.S. suffering from diabetes, and it is estimated that 798,000 new cases of diabetes occur per year in the U.S. alone [1,2]. About 20% of all diabetic patients have problems with their feet, and more than 50,000 patients have foot amputations every year. This number accounts for almost 60% of all non-traumatic amputations in the US. The survival statistics after amputation are as follows: 50% after 3 years and 40% after 5 years. Approximately $800 million/year is spent directly on hospital costs for the care of diabetic foot infections alone [3-5].

It is believed that elevated plantar pressure plays a major role in foot problems in diabetic patients. High pressures interrupt arterial blood flow [6], which is further compounded by the fact that diabetic patients lose sensory feedback from their feet, hence are not able to change their stance leading to unnatural pressure points. Formation of diabetic foot ulcers is a result of internal foot derangements, neuropathy, and peripheral vascular disease.

Neuropathy is the impairment of nerve functions. The cause is not known but is speculated to be a result of hyperglycemia. The accumulation of sugars is thought to form a "sheath" around the nerves. This can lead to dermal ulcerations, necrosis, and ultimately to partial or total amputation of the foot. The loss of feeling in the foot combined with the insufficient blood flow and alteration in the shape of the foot changes the pressure patterns applied to the foot sole. For healthy people, the pressure patterns are continuously changed by means of feedback from their mechanoreceptors. Diabetic patients are not able to do so, and may expose their feet to very high peak pressures, located at the same place and maintained for long times [7-10]. Out of diabetic amputees in the US, 61% of the cases were caused by neuropathy and 86% of the amputations could have been prevented [11].

The current treatments for this problem are custom-made shoe inserts, patellar tendon-bearing (PTB) braces, vitamins, faradic stimulations, rocker-bottom soles, surgical fusion, non-weight bearing cast immobilization and amputations [12]. The forming of the shoe implants requires means of pressure distribution measurements. These measurements are performed before the shoe implants are formed. After the implants are formed, they remain static in their form throughout their lifetime. These implants are designed such that pressures above 15-20 kPa are absorbed [6]. Since the foot changes its form, and the pressure patterns change over time, these inserts just cannot sustain their objective at all times.

A Comprehensive Foot Model

The development of the shoe-insert is dependent on the implementation of a comprehensive model of the foot structure. This would allow for a better understanding of the source of stresses, their location, the cause and effect of ulcerations, their eventual transition in to necrosis, the rate of increase of the problem, and a variety of other issues related to diabetic problems. There are models available in literatures that have begun to address some issues. Wojytra [13] developed a dynamic model for the walking gait of humans. Hence one could obtain the peak forces experienced by a person as he/she is walking under different circumstances. This model was implemented in ADAMS software (a multibody dynamic modeling software) as shown in Figure 1. The output of this model gives peak foot forces as shown in Figure 2.

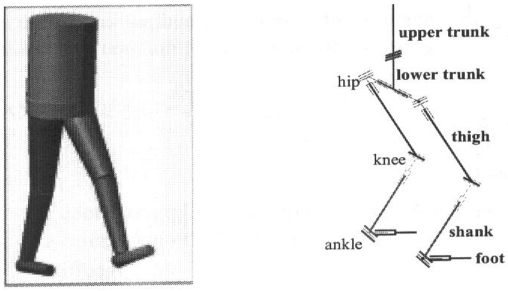


Figure 1: A dynamic walking model in ADAMS [13]

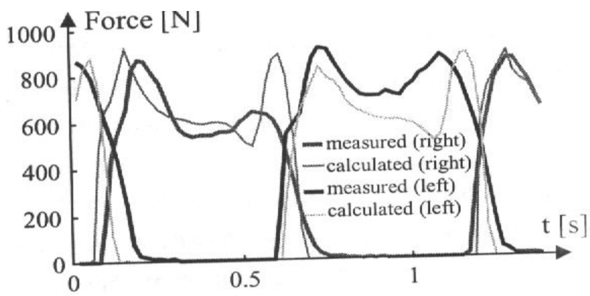


Figure 2: Forces Felt During Walking [13]

Gefen, *et al* [14] developed a much more detailed model that took in to account the skeletal geometry, ligaments and soft tissue, and were able to give stresses at different locations of the foot as well as different stages of the foot being in partial/full contact with the ground. This work was implemented in ANSYS (a finite element analysis software). It was also pointed out in the paper that a comprehensive model would help in the diagnosis and prognosis of diabetic foot ulcers. This model still needs to be extended to include the role of nerves and blood vessels so that a comprehensive model can be developed that not only predicts elevated stresses, but also predicts possible locations of dermal ulcers, and if possible tracks them over time. Therefore, the model to be completed will involve the physical aspects of the foot: bones, muscles, soft tissue, etc. in addition to a hemodynamic model as well as nerve activity effects.

Utilization of Smart Materials

A crucial aspect of the work outlined in this paper is the use of smart materials, for they can serve as actuators and sensors. Such materials include shape memory alloys, piezoelectric ceramics, piezoelectric polymers, magnetoreheological (MR) fluids, electrorheological (ER) fluids, electrochromic materials, optical fibers, tunable dielectrics and conducting polymers among others [15-19]. Shape memory alloys, for example, are being used to control the focus of solar collectors [20] or release devices for new spacecraft [21]. There is also a growing interest in biological systems and their relation to smart materials. Electroactive ceramic (EAC) materials are being commonly used as sensors and actuators, and find applications in sensing strains, vibrations, etc. as well as actuators to introduce vibrations or damp them out [22]. Probably the most promising smart materials for biomedical engineering applications are electroactive polymers (EAP) that induce a large strain under electrical activation [23]. The level of induced strain can be as high as two orders of magnitude greater than the striction-limited, rigid and fragile electroactive ceramics (EAC). Figure 3 shows the comparison of EAPs with other actuator technologies [23].

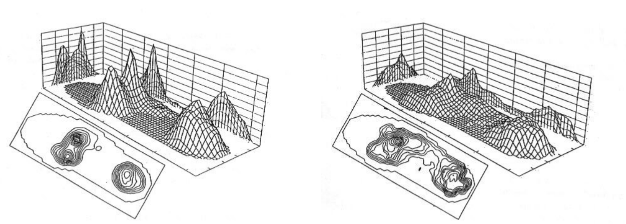
Comparison of EAPs with Other Actuator Technologies

Actuator Type (specific example)	Maximum Strain (%)	Maximum Pressure (MPa)	Specific Elastic Energy Density (J/g)	Elastic Energy Density (J/cm^3)	Coupling Efficiency k^2 (%)	Maximum Efficiency (%)	Specific Density	Relative Speed (full cycle)
Electroactive Polymer Artificial Muscle [1]								
Acrylic	215	7.2	3.4	3.4	~60	60–80	1	Medium
Silicone (CF19-2186)	63	3.0	0.75	0.75	63	90	1	Fast
Electrostrictor Polymer (P(VDF-TrFE)[2]	4	15	0.17	0.3	5.5	–	1.8	Fast
Electrostatic Devices (Integrated Force Array)[3]	50	0.03	0.0015	0.0015	~50	> 90	1	Fast
Electromagnetic (Voice Coil)[4]	50	0.10	0.003	0.025	n/a	> 90	8	Fast
Piezoelectric								
Ceramic (PZT)[5]	0.2	110	0.013	0.10	52	> 90	7.7	Fast
Single Crystal (PZN-PT)[6]	1.7	131	0.13	1.0	81	> 90	7.7	Fast
Polymer(PVDF)[7]	0.1	4.8	0.0013	0.0024	7	n/a	1.8	Fast
Shape Memory Alloy (TiNi)[8]	> 5	> 200	> 15	> 100	5	< 10	6.5	Slow
Shape Memory Polymer[9]	100	4	2	2	–	< 10	1	Slow
Thermal (Expansion)[10]	1	78	0.15	0.4	–	< 10	2.7	Slow
Electrochemo-mechanical Conducting Polymer (Polyaniline)[11]	10	450	23	23	< 1	< 1%	~1	Slow
Mechano-chemical Polymer/Gels (polyelectrolyte)[12]	> 40	0.3	0.06	0.06	–	30	~1	Slow
Magnetostrictive (Terfenol-D, Etrema Products)[13]	0.2	70	0.0027	0.025	–	60	9	Fast
Natural Muscle (Human Skeletal)[14]	> 40	0.35	0.07	0.07	n/a	> 35	1	Medium

Figure 3: Comparison of smart material properties

Selection of an Optimized Shape

Current passive inserts are effective in reducing high plantar pressures [6]. Figure 4a shows the pressure peaks that are felt by the foot of a diabetic patient. If this patient was to keep subjecting his/her foot to these pressures it could then lead to localized dermal ulcerations that can lead to necrosis. Figure 4b shows the modified distribution of the stresses by the use of a custom made shoe-insert, such that the maximum pressures are reduced by having a greater area of the foot bear the load. However, as stated previously, the ultimate aim of the proposed work is to further reduce the peaks in Figure 4b, as well as adapt to changing locations of these peaks.



(a) **(b)**

Figure 4: Before (a) and After (b) Treatment [6]

The average forces experienced by the human foot while walking has been fairly well documented. Figure 2 showed that the average peak force felt is approximately 800N. Now assuming that the average weight bearing area is around 200 cm^2, then the average peak stresses are in the range of 4.0 N/cm^2 or 40 kPa. This number can jump as high as 2500 kPa for a high jumper. It can be seen that even with a 10% increase in the contact area (from 200 cm^2 to 220 cm^2), the average peak stress can come down to 3.64 N/cm^2 or 36.4 kPa. This is almost a 9% reduction in the peak stress. In the most basic terms, this is the strategy that will be used to eventually solve the stress reduction problem. However, the problem is much more complex, and requires a systematic approach encompassing research, design work, simulations, experimental work and long term controlled studies.

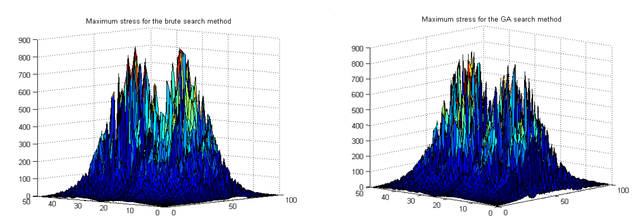
Shape Generation

The proposed shoe-insert is envisioned to contain 4-6 force sensitive resistors and 6-8 patches of a smart material that will be used as actuators. The force sensitive resistors will provide the system with a force profile acting on the foot. Since the smart material will be expanded and contracted according to an applied voltage, it will be necessary to specify the correct amount of voltage to actuate each patch. Different combinations of voltages will give different shape profiles, and the selection of the right combination of voltages to give the optimal shape is a difficult problem. It can be formulated as an inverse problem, i.e. one knows the region of high stresses, and one needs to shape the shoe-insert by applying the correct voltages to each actuator so as to obtain that shape. Closed-form solutions will be investigated, but currently the use of genetic algorithms are being explored to select the optimal shape voltages from a multidimensional space of the applied voltages.

The genetic algorithm will provide the mechanism for selecting the specific voltages that need to be applied to each of the patches by which to alter the shape of the entire insert for a respective stress scenario. Genetic algorithms have the ability to hone in on an optimum solution.

The first step in the use of a genetic algorithm is creating the initial population. The patches of smart materials will be placed at some combination of nodes on the insert. The nodes are being viewed as an array of numbers, in which each array position represents a specific height of the node. As a starting point, random numbers are inserted for each location, representing different node heights in the insert. Since some combinations are not physically possible, a specification of no greater than 10% variation between the node heights is needed to prevent neighboring nodes from being too great of a distance apart and resulting in sharp drop-offs. The size of the initial population desired will determine the third dimension for the three-dimensional array being used throughout the remainder of the genetic algorithm. For this study, a size of 100 was selected. This three dimensional array of node heights provides information for the new surface area of the insert. In order to find the stresses, the force profile obtained from the force sensitive resistors will be used. For the purpose of demonstrating that the GA is effective in producing the desired result, it is necessary to assume the force matrix at this time. As research progresses, the aforementioned model of the foot, or actual measurements, will ultimately provide the forces for this input. For each member of the population, a cost must be established. The cost function currently being used is the maximum stress added to the average stress for each member of the initial population. This will take into account the highest peak and also the overall stress for each member. The population is then sorted according to the cost and the bottom 50% will be discarded. In addition to sorting according to stress cost, it has been found that it is necessary to sort according to another characteristic. When the mating portion of the genetic algorithm takes place, it has been found that at times, two matrices were being mated that did not contain random numbers that were within the desired 10% variation. Consequently, the top 50 of the population were also sorted according to the average of the values of the random numbers for each population member. Now that the initial population has been evaluated and sorted, the remaining 50 can now be mated. The crossover point being used is the column width divided by two. This will result in each matrix being split into two equal halves. Each member is mated with the member in the next numerical position. For example, member 1 is mated with member 2 and member 3 is mated with member 4 and so on. The left half of member 1 is swapped with the right half of member 2 and vice versa. This mating takes place until all members are mated and a new population of 100 is present. Using the new population, the cost is again evaluated and the new population is sorted according to the same aforementioned procedure. Currently, 10 iterations of this process are being completed.

After using the Brute force method, the stress profile with the maximum stress is shown in Figure 5a. In this particular stress profile, there are two peaks of high stress. By using the genetic algorithm, the maximum stress is brought down by more than 5%, as shown in Figure 5b.



(b) **(b)**

Figure 5: Brute Method (a) and GA (b)

In order to verify that the stresses are indeed improving, the results of the GA search are tracked. The graph showing the improvements is shown in Figure 6. The average cost is shown as the upper curve while the minimum cost as determined by the genetic algorithm is the lower curve. Note, that the results are a typical run for a genetic algorithm that is

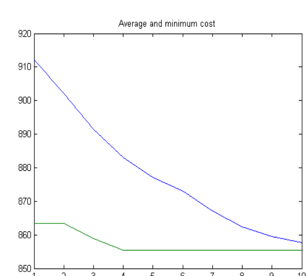


Figure 6: Average and Minimum Cost As Determined by the GA

working well. One does expect the average cost to come down as the algorithm runs through numerous iterations, and the one also expects the genetic algorithm to hone in to a minimum cost, which is also expected to go down. The shape selected (and developed) by the genetic algorithm is finally selected as the optimal shape to bring down the stresses.

Summary

This paper proposes a novel technique to reduce high foot pressure concentrations in diabetic patients by developing a novel shoe-implant, which a) provides regular stimulation to the foot so that the patient does not maintain one stance for a long period of time, and b) senses the pressure peaks and shapes its support so as to reduce them. The focus of this paper has been to show the preliminary use of genetic algorithms to select an optimal solution for the shape of the shoe-implant from a choice of almost infinite solutions created by different combinations of actuation voltages to discreetly place actuators. It has also been shown that by changing the shape of a shoe-implant the plantar pressures can be significantly reduced. This is particularly significant since the entire process may be done in real time.

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