CHARACTERIZATION OF A CUFF-BASED SHAPE MEMORY ALLOY (SMA) ACTUATOR

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Abstract: *This article proposes a novel cuff-based microactuator for automatic blood extraction using Shape Memory Alloy (SMA) technology. It aims to provide an actuator solution for an electronic mosquito-like device, e-Mosquito, which enhances blood glucose measurement to off the potential to significantly improve both the quality of life for diabetic patients and their disease management. Fabrication and assembly methods of the microactuator prototype are discussed. The 6-mm thick microactuator prototype underwent mechanical tests in a laboratory environment to characterize its penetration force and depth, which are the major factors facilitating skin penetration and blood extraction. Testing results demonstrated that this actuator can produce a maximum penetration force of 160gf and a maximum displacement depth of 2.45mm, which both exceed the minimum force and depth requirements for blood capillary-reaching skin penetration in humans. Five actuator prototypes were assembled and integrated to a cuff wrist strap. A pilot human study was performed to test the blood extraction capabilities of the device. All five actuators successfully penetrated the skin and drew whole blood samples appearing on the skin surface of the subject.*

Keywords: *BioMEMS, Shape Memory Alloy Actuator, Diabetes, Blood Extraction.*

ACM Classification Keywords: *J.3 Life and Medical Sciences.*

1. Introduction

1.1. Diabetes Mellitus

Diabetes Mellitus is a systemic disorder that results in elevated blood glucose levels due to insulin deficiency in the body, which can lead to many secondary complications [ADA, 2012a]. The disease affects over 400 million people worldwide and the numbers are continuously climbing. Type 1 Diabetes Mellitus (T1DM) refers to an absolute insulin deficiency due to autoimmune destruction of islet cells in the pancreas [ADA, 2012b]. The discovery of insulin by Banting in 1921 became a treatment for T1DM, which at that time was considered untreatable. Presently, T1DM patients account for about 10% of the

total diabetic population and are insulin-dependent throughout their lifetime. Type 2 Diabetes Mellitus (T2DM) includes individuals who have insulin resistance but incomplete insulin deficiency. T2DM accounts for about 90% of the total diabetic population [ADA, 2012a]. Of these patients, about 20% require external insulin-based maintenance similar to the one for T1DM patients. Over time, high blood glucose levels can lead to many diseases including kidney failure, nerve damage and blindness [CDACPGEC, 2013]. Both Type 1 and Type 2 Diabetes Mellitus require long-term maintenance, the goal of which is to achieve optimal glucose monitoring and control with the aim of decreasing the risk of vascular complications while minimizing daily glycemic variations [Hendriks et al., 2000].

1.2. Available FDA-Approved Glucose Monitoring Techniques

1.2.1. Fingerpricking Test

Standard blood glucose monitoring for diabetics relies on the fingerpricking test, a procedure in which a finger at its tip is pricked with a needle in order to obtain tiny amount of capillary blood for glucose testing by a sensor on a pen-like device. Although it is highly accurate for detecting blood glucose levels, fingerpricking test is painful and inconvenient. Therefore, patients, especially those who have developed visual impairment caused by diabetes (diabetic retinopathy), are often unable to adhere to the test schedule. As a result, the discontinuities in glucose monitoring limit the applicability of the fingerpricking test as a reliable tool in the intensive management of diabetes [Penfornis, 2011].

1.2.2. Continuous Glucose Monitoring

With the advances in implantable microelectronics, wearable devices featuring real-time continuous glucose monitoring (CGM) started to emerge on the market in the late 1990s [Penfornis, 2011]. CGM devices do not measure blood glucose levels. Instead, glucose levels in the interstitial fluid (ISF) are monitored by a needle-type sensor implanted subcutaneously. In the past ten years several companies released various CGM products, which include Abbott FreeStyle Navigator®, MiniMed Paradigm®, MiniMed Guardian® and DexCom SEVEN® PLUS. CGM is less invasive than the fingerpricking test. However, its accuracy is dependent on the equilibrium of glucose levels between ISF and whole blood. The balance between the two glucose levels further accounts for a time delay in the measurement and requires frequent recalibration using fingerpricking tests [Hoeks et al, 2011]. The price of achieving reduced invasiveness is the decrease in measurement accuracy. In particular, the false positive rate increases significantly due to sweating, temperature changes, electrostatic noise sources, etc., not to mention the invasiveness of the implantation of the ISF glucose sensor and the possibilities for infections [Hoeks et al., 2011]. For this reason, FDA approved the use of CGM as a supplementary technology to track the daily trends of glucose levels. Therefore, CGM does not replace the

fingerpricking test. For all commercially available CGM devices, the sensors must be re-calibrated by fingerpricking testing on the average about 4 times per day in order to maintain measurement accuracy.

1.2.3. Transdermal Sensors

Transdermal sensors feature technologies which measure glucose molecules extracted from the ISF across the skin barrier by applying physical energy [Oliver et al., 2009]. For example, the GlucoWatch (Animas, West Chester, PA, USA) was the first FDA-approved transdermal glucose sensor, which utilized reverse iontophoresis, a technique that applies low electric current across the skin between two electrodes to excite glucose molecules to pass across the dermis layer faster than due to passive permeability. Other types of physical energizers, such as low-frequency ultrasound and skin suction have been applied as well [Kost et al., 2000]. The main factors causing measurement inaccuracies are parasitic but electrically charged molecules on the skin surface due to concurrent phenomena such as sweating, temperature fluctuations, electrostatic noise sources, etc. [Hoeks et al., 2011]. Furthermore, the electrical current has been reported causing irritations by many users. As a result, the GlucoWatch was eventually withdrawn from the market in 2008.

1.3. Innovations in Glucose Monitoring and Management

1.3.1. Non-invasive Methods

Non-invasive glucose measurements refer to technologies that measure glucose levels in ISF without causing any tissue damage. Optical sensors use light of variable wavelengths to detect glucose and utilize different properties of light to interact with glucose in a concentration-dependent manner, which include scattering, thermal infrared, fluorescence, Raman, mid-infrared and near infrared spectroscopy, etc. [Oliver et al., 2009]. Good correlations were found in the measurements. However, significant differences remain with respect to comparative laboratory blood glucose measurements, due to the inter-subject variability in skin components. Presently, none of the optical sensors have become clinically accepted and approved by the FDA, based on inferior precision and reliability as compared to the standard fingerpricking measurements. Researchers have also tried to find the correlation between blood glucose level with glucose levels in other biological fluids which are easily accessible, such as tears [Yao et al, 2011] and saliva [Agrawal et al, 2013]. While these approaches make measurements easy, they are suffering from the interference caused by other biological molecules in the sample, which are dynamically changing and environment-specific [Smith, 2013].

1.3.2. Islet Cell Transplantation

It has been hypothesized that upon the transplantation of insulin-producing islet cells from a donor pancreas into another person [Piemonti & Pileggi, 2013], the donor's islet cells can start producing

insulin to regulate blood glucose levels in the recipient's body. The concept of Islet Cell Transplantation is not new, but still remains an experimental treatment for T1DM. Two important limitations preclude its widespread application: (a) donor's islet cell rejection by the recipient's immune system is unavoidable and the transplant recipient must remain on immunosuppressant drugs [Lakey et al., 2003]; and (b) the limited supply of islet cells available for transplantation. As a result, only 471 T1DM patients were recorded receiving islet cell transplantations worldwide in the five-year period from 1999 to 2004 [Shapiro, et al., 2005]. Replacing human islet cells for transplantations with piglet islet cells only aggravated immunological rejections [Elliott, 2011].

1.3.3. Stem Cells Transplantation

Stem cell therapy for diabetes hypothesizes that patient's own stem cells can differentiate themselves into a set of islet cells which subsequently can be transplanted into the patient to produce insulin [Pagliuca, et al., 2014]. In theory, stem cell therapy can address the two problems of the islet cell transplantation approach, because there is no immunological reaction to the patients' own cells and there are plenty of stem cells suitable for the therapy. The main challenge to this new approach is that some stem cells differentiate into tumors after transplantation. This option will remain an experimental treatment until this problem is fully addressed [El-Badri & Ghoneim, 2013].

1.4. The Concept of the Electronic Mosquito

There is an obvious need for minimally-invasive blood sampling devices which would be able to automatically obtain and analyze a series of static whole blood samples over an extended period of time with minimal pain and limited user intervention. E-Mosquito is a nature-inspired concept which is implemented with advanced MEMS technologies. Its first generation was introduced about 10 years ago [Gattiker et al., 2005]. The original idea was to implement a skin-patch device which included a set of single-use cells. Figure 1 shows the detailed mechanism of an e-Mosquito cell. The device can be tightly adhered onto the skin and contains a precisely controlled actuator, which delivers a sufficient force to drive a microneedle to penetrate under the skin. A whole blood sample can be extracted as a result of the natural blood pressure gradient in the penetrated capillary vessel. A glucose sensor measures the glucose level of the extracted miniscule static whole blood sample and the signal is then sent by an RF transmitter for post-processing and display after Analog-to-Digital conversion. Each e-Mosquito device carries multiple cells of single-use needle-sensor assemblies which are to be replaced daily.

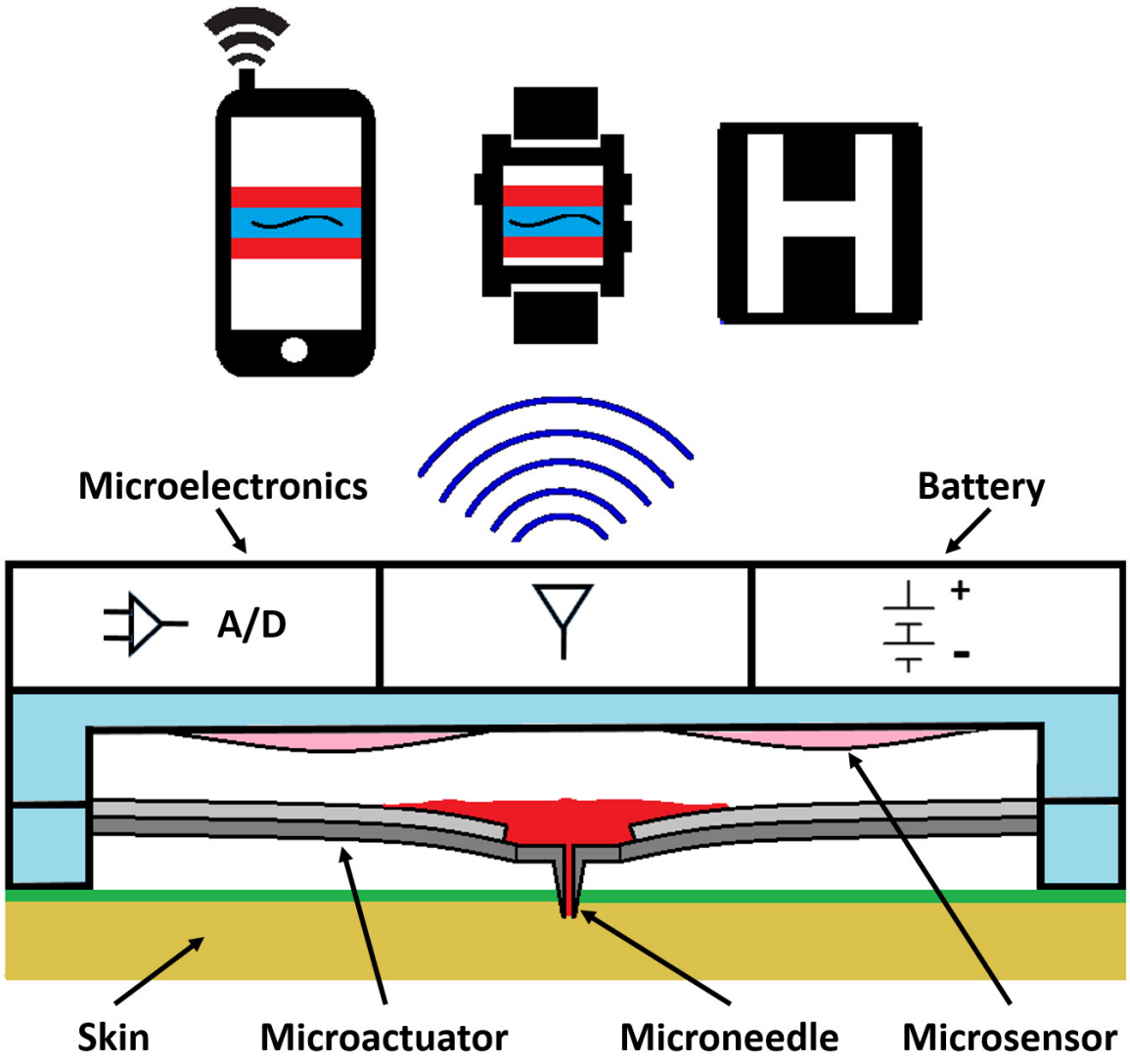

Figure 1. A single cell of the first-generation e-Mosquito prototype

In its macro-size first-generation prototype, the e-Mosquito utilized a pair of piezoelectric actuators which exerted a force of nearly 100 gf with a maximum stroke of 1.25mm [Gattiker, 2006]. An upgraded version of this system further incorporated an impedance sensor detecting the presence of a blood sample to form a closed-loop control of the actuator. It successfully extracted a blood sample of 10μl in a chicken model test [Thomas, 2009]. However, several design problems hampered its commercialization feasibility. First of all, the piezoelectric actuators required a high driving voltage of up to 60V. To achieve this voltage, additional electronics had to be integrated into the device, which greatly increased its thickness. In addition, the actuation design was not reusable due to sanitization

requirements. The expensive piezoelectric actuators had to be disposed of after use, which made the device unaffordable.

The main barrier for acceptable clinical use of the first-generation e-Mosquito device was the lack of a compact, yet effective actuator to painlessly and regularly withdraw blood samples from subcutaneous capillaries. With space and energy constraints for wearable devices, it is not easy to insert a needle about 1mm below the skin where capillary vessels are abundant.

1.5. Aims of the Present Paper

This article aims at proposing a shape memory alloy (SMA) in-plane microactuator to be integrated with a miniaturized blood glucose sensing circuit and control unit in a cuff-based blood glucose monitoring device. A precise instrument is implemented to quantitatively verify that the performance of the actuator meets the requirements for capillary-reaching skin penetration. The skin penetration capability was also studied in a pilot in-vivo human experiment.

2. Methods

2.1. Design Criteria for A Microactuator for Blood Extraction

The microactuator has to meet a minimum of four pivotal design constraints to successfully fulfill its purpose as the major building block of a second-generation e-Mosquito device.

First of all, its thickness has to be restricted within millimeters in order to save space for other components of the e-Mosquito device. Therefore, the aim is to make the thickness of our microactuator to be around 6mm.

Second, the maximum penetration depth has to be big enough to reach the depth level where capillaries are abundant (0.8~1.5mm, [Hendriks et al., 2000]).

Third, the penetration force exerted on the microneedle must be sufficient to pierce through the force-resistive layers of the skin. An intensive literature review concluded that the minimum lancing force to penetrate the skin surface is approximately 30gf [Tsuchiya et al., 2005].

Fourth, the microactuator has to be easily integrated with the actuator control, glucose measuring and other building blocks of the e-Mosquito device.

There are several other secondary requirements for the actuator design, including low manufacturing cost, easy assembly procedure, biocompatibility, etc.

2.2. Cuff-based e-Mosquito Blood Glucose Monitoring System

2.2.1. Design Overview

Figure 2 shows a computer-aided design (CAD) drawing of the proposed cuff-based, two-cell e-Mosquito device. The substrate of the cuff is made of silicon rubber, which is the common material for wrist watch straps. The cuff is designed to be worn on the users' arms or wrists. This new design features a wire-like SMA microactuator which replaces the piezoelectric actuator from the first-generation e-Mosquito device. Once heated above its transition temperature (usually by supplying an electrical current), the crystal structure of the SMA transforms from one state to another, which results in a macroscopic shrinkage by up to 8% of its original wire length. The energy released during the transformation exerts a longitudinal contraction force. Because of its shape flexibility, the SMA wire is wrapped circumferentially around the cuff surface, with its two ends connected to a power supply and electronic control circuitry on the opposite side of the cuff. This design saves space for the integrated glucose measurement circuit and reduces the overall thickness of the cuff to 6mm, as depicted in Figure 2 (right).

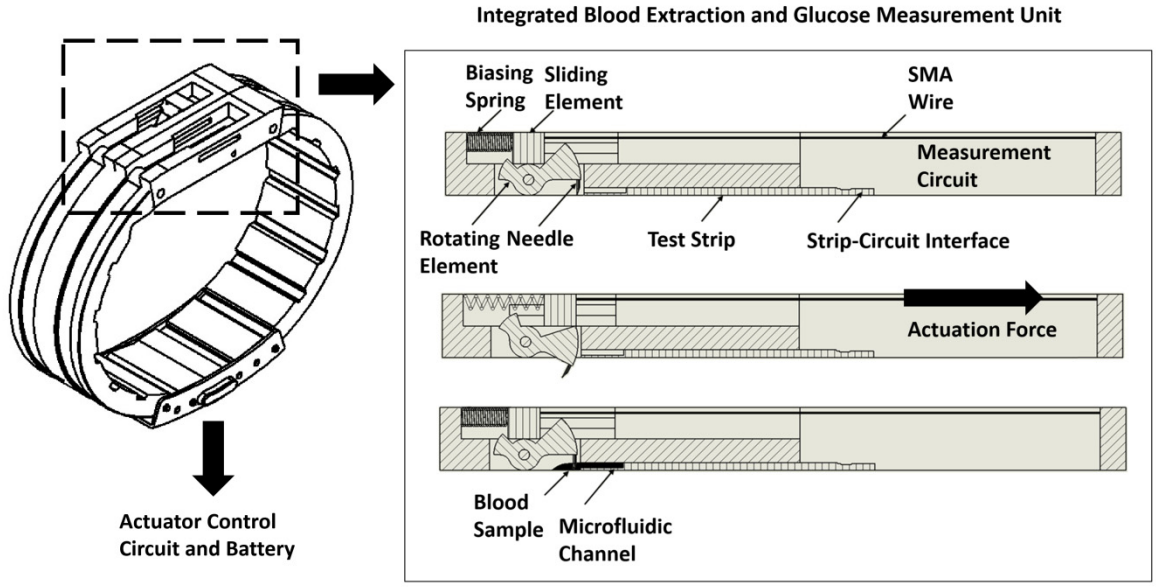

Figure 2. A conceptual prototype of the cuff-based e-Mosquito device (left); the device features a blood extraction unit utilizing a Shape Memory Alloy micro actuator (right).

2.2.2. In-plane Needle Penetration Mechanism – A Closer Look

Figure 2 depicts a simple in-plane needle-penetration mechanism, which consists of four components: a sliding element, a rotating element, a biasing spring and a needle in a planar alignment. The in-plane SMA wire is mounted on one side of the sliding element, whereas the biasing element is mounted on the opposite side of it. The sliding element is engaged with the rotating element so that when the sliding

element slides under the actuation force of the contracting SMA wire, it pushes the rotating element to turn around an axis. A needle mounted on the rotating element moves off the plane and pierces into the skin at a pre-determined angle. When the shape memory effect of the SMA fiber is removed, the biasing element retracts the sliding element, which pushes the rotating element and the attached lancet back to its original position on the plane. Upon successful needle penetration reaching a capillary vessel, a small volume of blood emerges at the surface of the skin after the retraction of the needle. By capillary force, the blood flows into the microfluidic channel of a standard test strip positioned in the vicinity of the needle. The integrated glucose measurement unit then reads the glucose level in this blood sample using a standard potentiostat circuit [Wang, 2008]. The cells can be directly disposed once they are used up.

2.3. Fabrication and Assembly

The fabrication cost was taken into consideration during the prototyping process. Instead of micro-machining the microactuator components, compression molding was chosen as the prototyping method. The mold was made of stainless steel by a micro-machining system (OM-2, HAAS Automation, Oxnard, CA, USA) with a positioning accuracy of ±0.5μm and a resolution of 0.1 μm. The actuator body, sliding element and rotating element were all designed to be of equal thicknesses. Therefore, their molds were machined on the same stainless steel sheet (Figure 3).

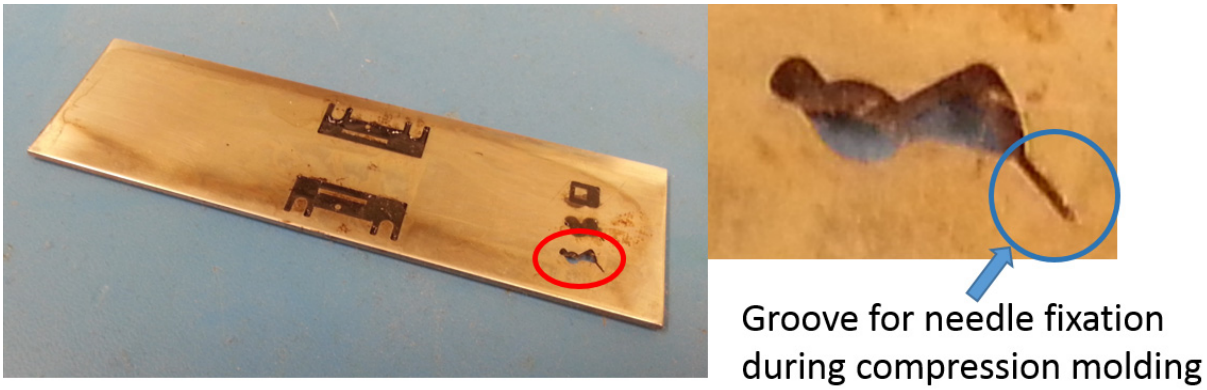

Figure 3. The mold of the actuator body, the sliding element and the rotating element (left); an enlarged photo of the circled area features a groove for needle fixation during compression molding (right).

A thermoplastic material, acrylonitrile butadiene styrene (ABS, HI-121H, Chimei, Qingdao, China), was chosen as the charge material (i.e. the plastic material that fills the mold cavity) of the compression molding because of its biocompatibility, high stiffness, good heat resistance and relatively low cost. The compression molding was performed on a manually operated four-post compression molding machine (Model 4122, Carver, Wabash, IN, USA) in approximately 30 minutes for each cycle. A 0.4mm-wide

groove was machined at the front end of the rotating element for affixing a standard 33-gauge microneedle. Due to the small width of this groove, the ABS charge did not flow into it during the compression molding process. Therefore, the needle tip remained exposed and sharp after the molding.

Seven sets of the plastic components were manufactured. They were assembled with the SMA wire (BMF150, Toki Group, Tokyo, Japan) and the biasing spring (EI007A01M, Lee Spring, Brooklyn, NY, USA, Spring rate: 17gf/mm) into seven actuator cells. Two actuator cells were used for the characterization (See Section 2.4.) and five others for the pilot human study (See Section 2.5.).

2.4. Characterization of the Microactuator by A Mechanical Test Station

In most applications, SMA microactuators are activated by a voltage supply. In the present application, the voltage supply was set at a constant 3V as suggested by the SMA actuator manufacturer. However, the voltage-dependent displacement and force curves of SMA actuators have been reported to be strongly nonlinear and to exhibit hysteresis [Lee & Lee, 2000]. Furthermore, heating and cooling processes during SMA wire fabrication are usually not precisely controlled [Senthilkumar et al., 2011]. This can result in a variation in the mechanical properties of individual SMA wires from different production batches. Therefore, mechanical testing is still the most accurate way to characterize SMA actuators. We adapted a mechanical test instrument design [Chikkamaranahalli, et al., 2005] for SMA actuators, with a particular emphasis on the biasing spring. As shown in Figure 4, one horizontal load cell (XLUS88, Tecsis, Worthington, OH, USA) and a linear variable differential transformer (LVDT) sensor (MHR250, MSI, Hampton, VA, USA) monitored the in-plane actuation force and displacement of the needle.

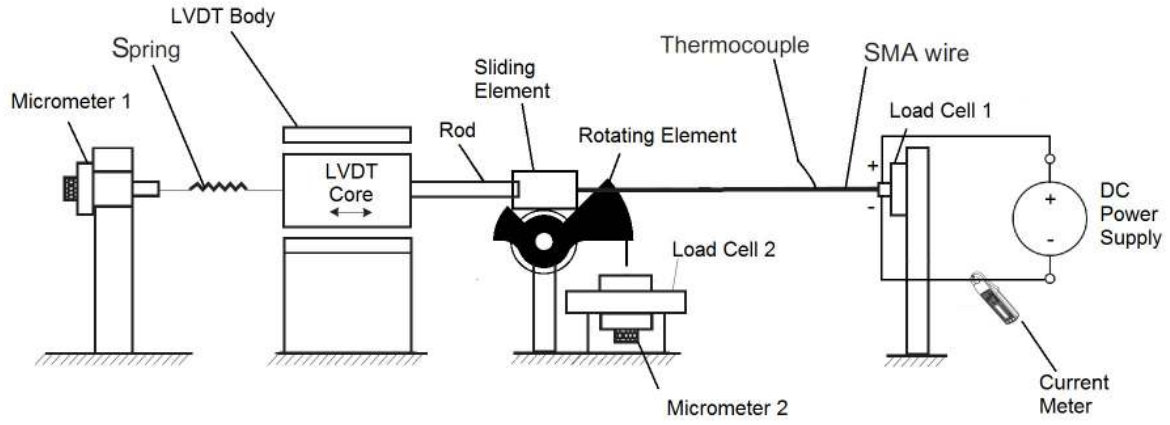

Figure 4. The mechanical test station for SMA microactuator characterization

A vertical load cell was added to the test station to keep track of the vertical force exerted by the actuator at the tip of the needle. A thermocouple (SMCJ-T, Omega, Stamford, CT, USA) and a current meter (CC-650, Hantek, Qingdao, China) provided peripheral measurements to detect whether the SMA actuator was functioning properly. A horizontal micrometer (261L, Starrett, Athol, MA, USA) was used to adjust the position of the microactuator components before each measurement. By adjusting the depth of the vertical load cell using the vertical micrometer, the penetration force of the needle at various depths was obtained.

Figure 5 shows the experimental setup of the synchronous data acquisition and control block. The central data transmission and acquisition module was implemented by a data acquisition (DAQ) card (NI-6024E, National Instruments, TX, USA) which includes a built-in timer that accurately synchronized the actuator control and monitoring processes. The input and output functions of the DAQ cards were controlled by industry-standard software (CVI, National Instruments, TX, USA). Customized analog amplification and conditioning electronic circuits for each sensor in the mechanical test station were developed for optimally utilizing the analog range of the input channels of the DAQ card. The sampling rate was set to 1 kHz for all sensors. Sensor data were stored for offline statistical analysis.

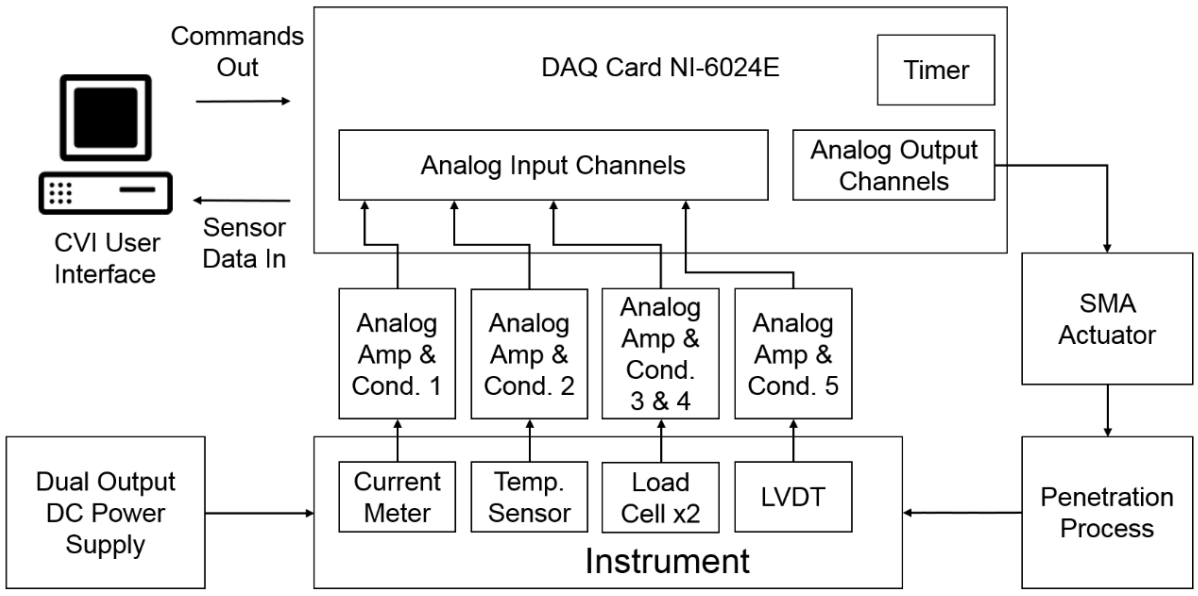

Figure 5. Block Diagram of the Control and Monitoring System

2.5. Blood Extraction Testing

One actuator cell was mounted on silicon rubber cuff (Zoro, Burnaby, BC, Canada) using miniaturized screw-and-nut mechanisms (Figure 6). The SMA wire was wrapped around the cuff and connected to a 3V DC supply via an electrical switch, which turned on and off the actuation circuit during the test. One

subject (28-year old male) was recruited for the pilot blood extraction testing and signed an informed consent form. The subject was instructed to wear the cuff on his forearm and to adjust the tightness of the cuff so that the bottom surface of the actuator was in full contact with the skin surface while the cuff tightness remained at a comfortable level for him. The electrical switch was closed for 10 seconds to activate the SMA actuator during this period of time. Subsequently, the subject was instructed to remove the cuff and observe the penetration site to check if a transcutaneous bite was present and blood emerged from the bite. This test was repeated 5 times on the same subject at different locations on his left forearm.

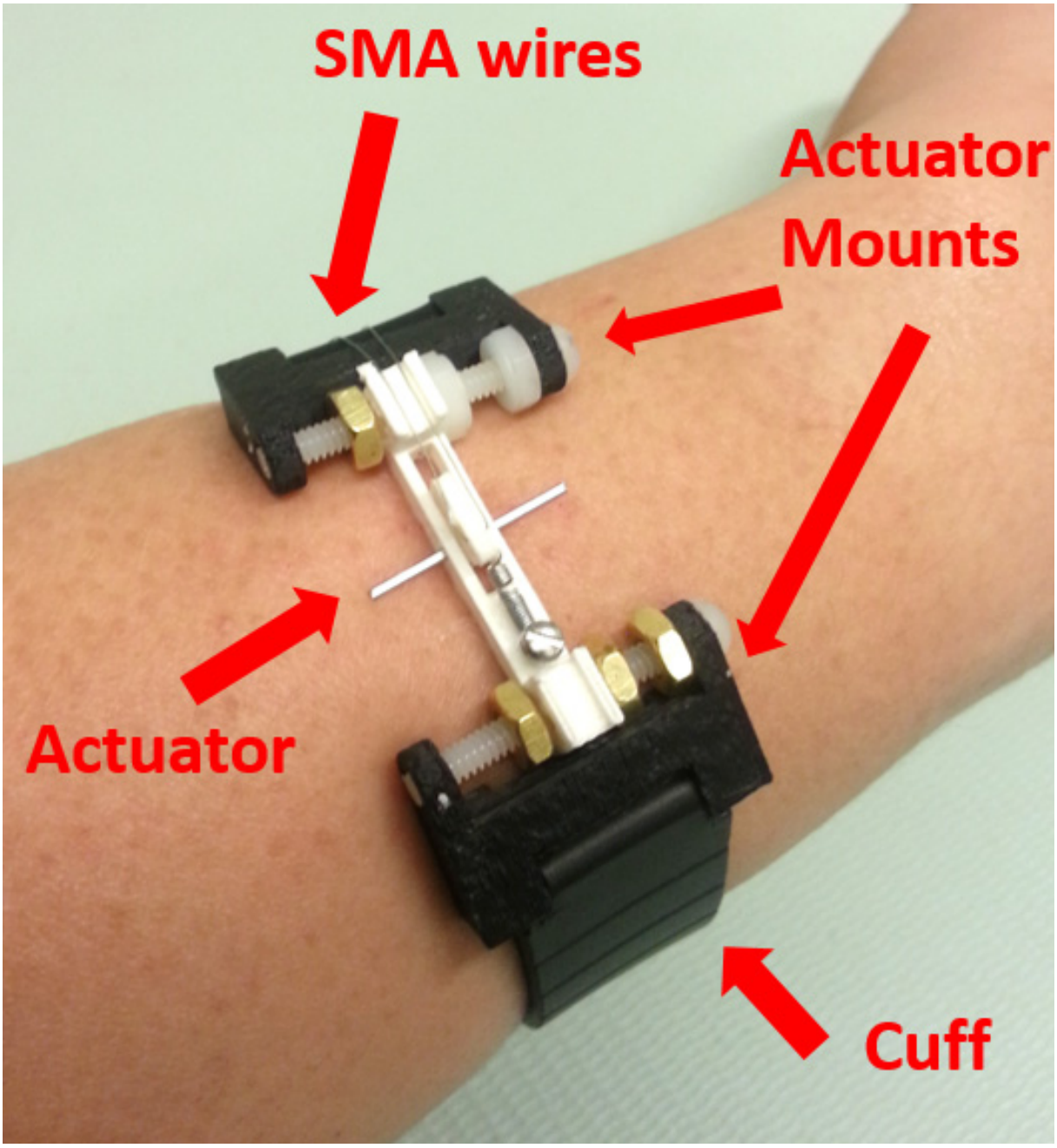

Figure 6. A functional prototype of the e-Mosquito actuator worn by the human subject on his forearm

3. Results

3.1. Prototype Implementation

Seven sets of the e-Mosquito actuator components were successfully fabricated using compression molding. The cells were assembled easily utilizing the miniaturized screw-and-nut mechanisms. Table 1 shows a breakdown of the material cost per SMA microactuator. Currently, the total cost per actuator is $3.60. This number can be easily reduced to less than $2.00 when mass-produced.

Table 1. Material cost breakdown per SMA microactuator

	Name	Unit Price ($/Unit)	No. of Units	Price
1	SMA wire	$20.00/meter	0.1 meter	$2.00
2	Biasing spring	$91.30/ 100 pcs	1 piece	$0.91
3	ABS molding granules	$2.5 / kg	0.003 kg	<$0.01
4	Gauge-33 hypodermal needle	$2.99 / 10 pcs	1 piece	$0.30
5	Mounting threaded rod and nuts	$0.19 / pair	2 pair	$0.38
	Total			**$3.60**

3.2. Characterization

We aimed to quantify two important aspects of the SMA microactuator: (1) Maximum displacement depth; and (2) Penetration force along the path of the needle movement. These two characterization tasks were accomplished by two sets of experiments using the mechanical test station.

3.2.1. Maximum Displacement Depth

The actuator was powered down and the needle was reset to its original position. Subsequently, the vertical load cell was moved 2mm below the needle position, which was used as the starting depth. At this depth, the actuator was activated 5 times. During each time, the load cell output was observed. If there was a change in the output, a counter increased by one, which was recorded into an Excel datasheet. Then, the depth of the load cell was increased by 0.025mm and the steps above were repeated at the new depth. The measurements eventually stopped at a depth of 2.5mm below the needle position. The entire test was repeated on a second SMA microactuator. Figure 7 shows a plot of

the number of successful needle displacements reaching various depths recorded from the two actuators. It can be observed that the maximum penetration depth achieved by both actuators reached 2.275mm. The minimum repeatable displacement depth was not less than 2.175 mm, which was deeper than the targeted goal (0.8~1.5mm).

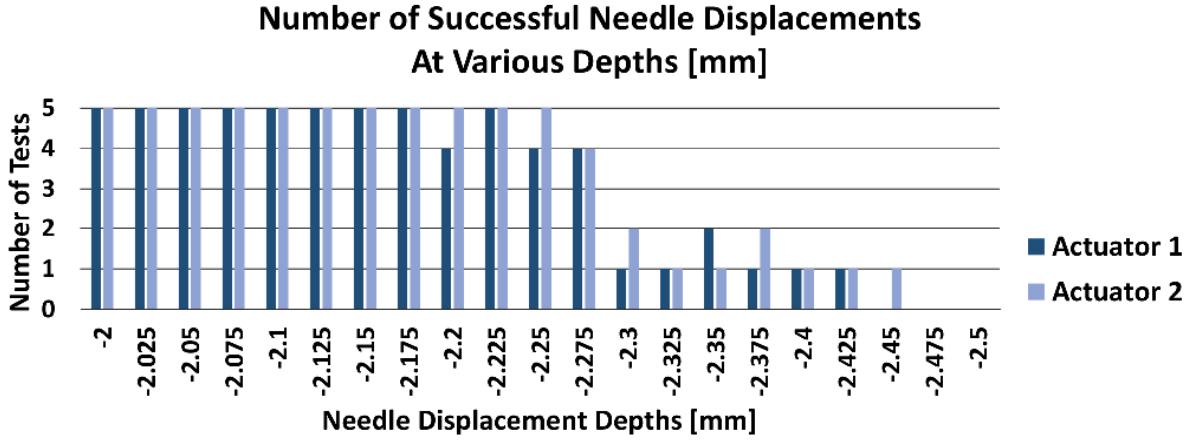

Figure 7. Maximum penetration depths of two SMA actuators (5 separate tests)

3.2.2. Penetration Force

Due to the biasing force of the spring and the change in the penetration angle during the rotation, the vertical penetration force changes at various depths below the skin surface. Therefore, the maximum exerted force of the SMA actuator alone cannot provide sufficient data to fully characterize it. In particular, force resistances of different layers of the skin vary. The top skin layer (the stratum corneum) is the most force-resistive layer compared to the layers below it [Hendriks et al., 2000]. Therefore, it is necessary to determine the penetration forces at various depths.

As described previously (see Section 3.1.), the depth of the vertical load cell can be adjusted by the micrometer mounted on it, which allows monitoring the penetration force at different depths. At the beginning of the expriment, the load cell surface was moved up to the same level as the needle's original position. Then, the SMA acutator was triggered twice. Each time, the actuation lasted 10 seconds and the maximum penetration force during these time periods was recorded into an Excel spreadsheet. Subsequently, the load cell depth was increased by 0.025 mm and the two maximum penetration forces observed at that depth were recorded again. This entire process was repeated from zero depth to the maximum displacement depth that was determined in Section 3.1. (

Figure **8**).

It can be observed from

Figure **8** that the penetration force gradually reduced as the displacement grew deeper, despite its volatile trend at shallow depths. The unstable force-depth trend at shallow depths could be explained by the hysteretic nature of the SMA microscopic transformation at low strains [Kohl, 2004]. It is possible that rapid local temperature rise leads to an explosive contraction which peaked during the recording time. The force-depth trend tended to get stabilized at deeper depths when that hysteretic period was over. The gradual reduction of the penetration force along the displacement was due to the linearly increasing biasing force by the gradually extending spring. Another reason might had been related to the increasing angle between the penetration force vector and the vertical direction as the needle moved deeper. This stems from the fact that the force measured by the load cell represented only the Z-axis component of the penetration force. Therfore, the actual penetration force at these deeper depths could had been higher than what was measured by the load cell.

Figure **8** shows that the forces were generally larger than the minimum force required for penetrating the skin [Tsuchiya et al., 2005]. The penetration force was stronger at the beginning of the penetration and consistently dropped along the penetration. This is advantageous to this particular application because the largest force is required at the top skin layer.

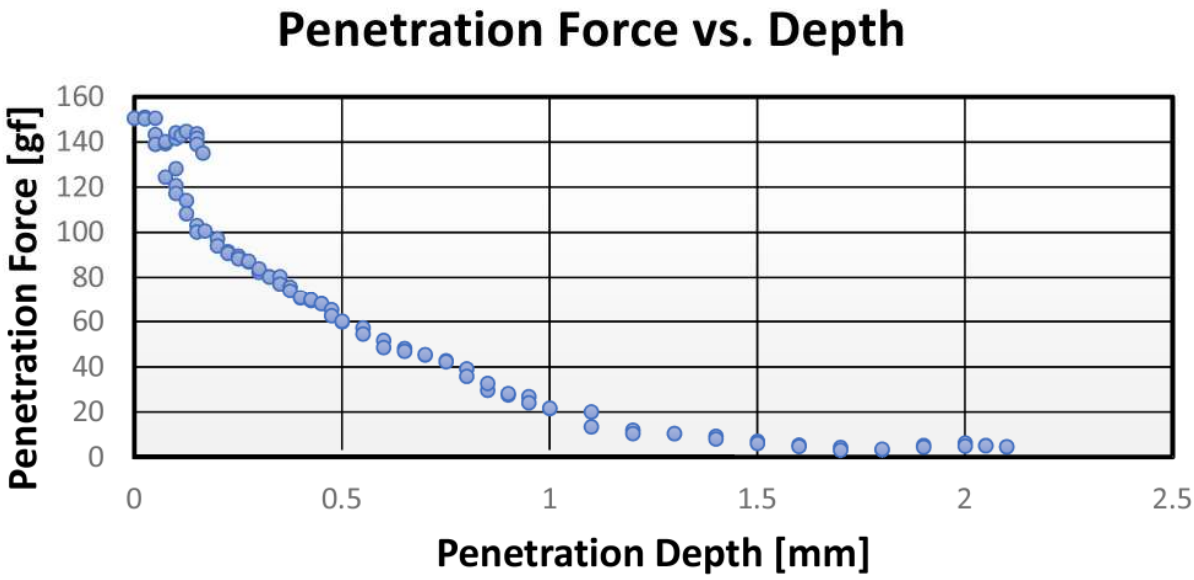

Figure 8. Penetration forces monitored by the load cell at various penetration depths

3.3. Blood Extraction Testing

The cuff-based device was removed from the subject immediately after the SMA actuation. A subsequent visual observation of the penetration site was performed for one minute after the SMA

actuation. In two out of the 5 tests, a drop of blood autonomously emerged at the skin surface during the one minute. In the other three tests, a drop of blood was formed at the skin surface by mildly squeezing the skin around the penetration site. Therefore, it can be concluded that the SMA actuator successfully penetrated the skin in all of the 5 tests based on these visual observations.

Figure **9** shows a drop of blood that emerged at the skin surface after one test.

Figure 9. The SMA actuator at the activated state (left); a drop of blood (~1mm in diameter) was observed emerging at the skin surface after the device was removed (right).

4. Discussion and Future Work

An SMA microactuator was proposed for the e-Mosquito, an automatic blood extraction device aiming to provide minimally invasive glucose monitoring for diabetic patients. The actuator was prototyped and preliminarily tested in laboratory setting. There are several important issues which have to be addressed in the future. Repeatability tests on the penetration forces and depths of the proposed SMA microactuator are needed in order to statistically determine whether they meet the minimum requirements for skin penetration and blood drop extraction without any additional mechanical manipulations in humans. Considering the hysteretic nature of the SMA microscopic transformation, more experiments are necessary to better characterize this microactuator.

The feasibility of this innovative SMA actuator design for automatic blood sampling has been demonstrated in a pilot in-vivo human testing. The SMA actuators exerted sufficient force to penetrate the skin barrier and reached the capillary vessel during these 5 tests. However, the blood automatically emerged on the skin surface only in 2 out of the 5 tests. Even in these two tests, the volume of the blood samples that were observed at the skin surface seemed not sufficient for an accurate test strip

testing. The small blood volume could be related to the small diameter of the 33-gauge microneedle, which was demonstrated before [Fruhstorfer et al, 1999]. In the future, microneedles with bigger diameters can be tested using the same SMA actuator. Quantitative methods have to be implemented to determine the blood volume.

Conclusion

This article proposed a novel cuff-based microactuator for automatic blood extraction using SMA technology. It aimed at providing an actuator solution for the e-Mosquito device, which could significantly enhance the quality of life for diabetic patients as well as improve their disease management. Fabrication and assembly of the microactuator were discussed. The microactuator prototype underwent some mechanical tests in laboratory environment to characterize its penetration force and displacement depth. The test results showed that this actuator met the minimum force and depth requirements for skin penetration. The feasibility of this innovative SMA actuator design for automatic blood sampling has been demonstrated in a pilot in-vivo human testing, in which the SMA actuators successfully penetrated the skin barrier and reached capillary vessels. Optimization of the needle assembly combined and quantification of the blood extraction capabilities of the actuator are needed.

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