Simulation Analysis of a Conformal Patch Sensor for Skin Tension and Swelling Detection

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***Abstract*—Intravenous cannulation (IV) has a potential medical complication known as extravasation which arise when the fluid accumulates in the subcutaneous tissue layer causing skin swelling symptom. The cost incurred for the addition hospitalization stay and treatment due to the extravasation complication is high. The current detection devices for extravasation is expensive, bulky and it is not suitable for the daily routine IV cannulation administration. In this work, a wearable and conformal sensor patch was developed for detection of skin swelling and tension. Structural simulation analysis and ex-vivo characterization of thin film metal (Ti/Cu/Au: 20 nm/ 2 µm /20 nm) were performed and result were presented in the paper. The sensor patch was able to detect skin tension and swelling of less than 3mm deformation height caused by 2-ml of fluid infusion. The sensitivity of the electrode sensor was 45% change of resistance per ml volume of infused solution.**

Keywords- Swelling, extravasation, intravenous cannulation, sensor patch

I. INTRODUCTION

Skin swelling is an accumulation of the fluid in the body. It is a common complication also known as extravasation injuries which arises from intravenous (IV) cannulation procedure. During the procedure, the medication or fluid was not properly delivered to the patient's vein, the fluid entered and accumulated in the subcutaneous tissue layer instead. This accumulation resulted in the skin swelling and tension which lead to pain and discomfort for patient. It might lead to a more adverse complication such as tissue death with possible deformity or long term functional impairment. The severity is dependent on the type of medication or fluid being administrated and the volume extravasated into the subcutaneous tissue before being detected by the clinicians. For instance, fluid with glucose concentration of 10% or more; fluid which contains potassium, calcium and sodium bicarbonate and contrast agent for computed tomography (CT) procedure or chemotherapy drugs are highly toxic and will cause skin necrosis when extravasated [1][2][3]. In the event where highly toxic chemotherapy drugs with more than 5ml are being leaked from the vein to the surrounding tissue, it will cause severe damage to the tissue and required immediate medical intervention. Therefore, there is a need to detect such swelling as early as possible to minimize the adverse effect.

A market survey with intensivists, head of nursing and pediatric surgeon from North America, European Union (EU) and China (Shanghai and Beijing) had been conducted. The survey includes the data on annual IV cannulation procedure being carried out in hospital, the estimated the incident rate and complication cost incurred for extended hospitalization due to extravasation incident. There is an estimated annual incident rate up to 6% in North America and EU, which correspond to an estimated up to 3.8 million and 5.1 million cases respectively. For China, there is an approximation annual incident rate up to 10% which is 5.6 million cases. The extended hospitalization stay and cost incurred per case was approximately up to USD$ 50,000 for North America, Euro € 30,000 for EU and USD$ 15,000 for China. This survey has shown that there is a huge market for device that could detect extravasation incident early for routine IV cannulation and help to reduce the additional cost incurred.

One of the target patient groups for our work is the newborns and infants. 70% of the extravasation cases occurred in neonate [4]. An approximation of 4% neonate in the intensive care unit had retained serious scarring due to extravasation injuries [5]. This particular group of patients is at a higher risk of developing extravasation injuries. As compared to adult patient, this group of patient has less subcutaneous tissue, their skin are still not fully developed or mature and they have very small and fragile veins [6]. Furthermore, this group of patients is unable to communicate with their caregiver on the pain experienced by them due to extravasation injuries. Therefore, extravasation incident will often went unnoticed by the caregiver and lead to adverse complications. The complication will requires surgical skin grafts, therapy to address any physical limitations associated with scarring, and might result in loss of limb[7][8].

The current extravasation detectors are used in chemotherapy and during CT scanning procedure to detect and prevent extravasation incident for occurring. These devices are mostly expensive and cumbersome to use [9]. For instance, Bayer healthcare's detector device is being sold as an accessory to a CT injector system. Another example of extravasation detector is from ACIST medical system. This system uses a sensor patch applied at the contrast agent injection site to monitor the skin impedance. For routine IV cannulation such as fluid, medication and parenteral nutrition administration, there is no such commercial extravasation detector technology available. The unmet clinical needs in this case are the current devices being expensive, bulky and

not meant for the daily routine IV cannulation administration [9].

To address the unmet clinical need, a stretchable sensor patch which is wearable, portable and cost effective in routine IV cannulation for the early detection of extravasation was developed. The sensor patch is able to detect the skin tension and swelling resulted from as low as 2ml of fluid accumulation. Ability to detect extravasation early as possible will help to reduce the potential damage to the surrounding tissue and ensure that the drug was administrated properly to the patient; failure in the cannulation will jeopardize the medical management and compromise patient care.

II. Design Overview

For routine IV cannulation procedure, the cannula is being inserted into the patient's vein for drug or fluid delivery. An adhesive urethane polymer film, tegaderm film, is placed over the cannula needle to secure the needle at the cannulation site. For our proposal, there will be no change or any addition step required for the routine IV cannulation procedure. In this work, the sensor electrodes are patterned onto the tegaderm film which adheres onto the patient's hand at the cannula site. The function of the sensor electrode on the tegarderm film is to detect swelling in the skin tissue. Figure 1. shows the schematic of the sensor patch system for detection of skin swelling.

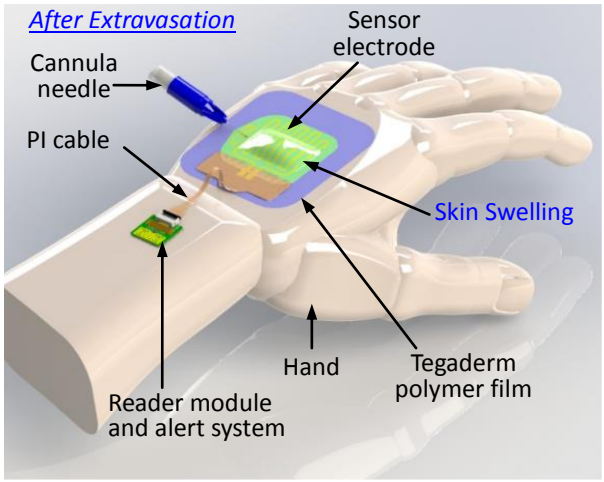

Figure 1. Schematic of sensor patch system for skin swelling detection

In the event when the cannula needle moves out from the vein into the subcutaneous tissue layer, the drug and fluid will accumulated and resulted the increase in the skin tension and swelling. These will stretch the sensor electrode on the polymer film and cause a change in the resistance value of the sensor. The resistance value of the sensor electrode will be measured and recorded into the reader module. This reader module is programmed to measure and record the initial resistance value of the sensor electrode as the baseline for the detection mechanism. Different resistance threshold limits setting is programmed into the reader module. Once the resistance value of the sensor patch changes and reached the predefined threshold due to the skin swelling, the reader module will activate the alert system to the clinician for immediate checking on the cannula site and medical intervention as required.

III. Simulation

Structural simulations to analysis the stress, strain and deformation of the sensor patch were conducted using ANSYS finite element analysis. Three-dimensional model of the patch was created with boundary conditions being applied. The first step for simulation is to create the model of the sensor patch using SolidWorks software as shown in Figure 2. The thickness of the sensor electrode used for the simulation is 2µm and 5µm respectively.

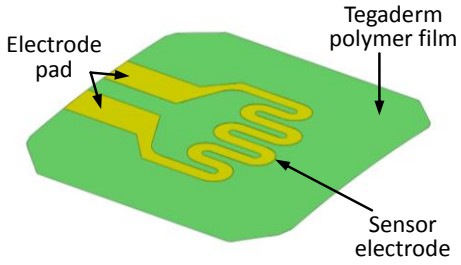

Figure 2. SolidWorks model of sensor patch

Deformation of the sensor patch using a spherical object of diameter 20mm and at a 5mm z-directional deflection was used to simulate the skin swelling due to fluid accumulation. Material properties of the polymer film and the metal traces used for the simulation are shown in TABLE I. Figure 3 shown the simulation deformation result of the 2µm thick sensor electrode. The sensor patch is able to achieve a maximum deformation of 5mm in the z-directional. 5µm thick sensor electrode deformation result shows similar result as 2µm thick sensor electrode.

TABLE I. Material Properties

Material	Mechanical Properties	
	Young's Modulus	*Possion's Ratio*
Tegaderm film (PU)	3.6 MPa	0.4
Copper	110 GPa	0.4

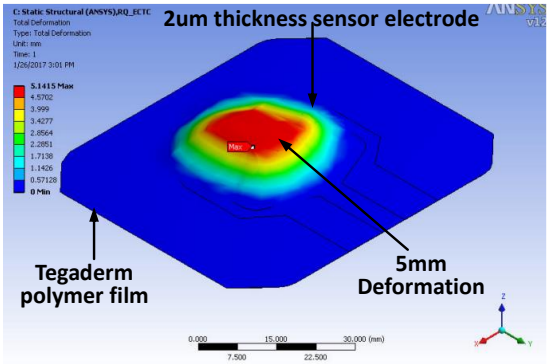

Figure 3. Deformation simulation result for 2mm thick sensor electrode

After the deformation simulation had been completed, the next simulation phase was to analyze the stress and strain

simulation develops along the electrode traces and the adhesive film during such deformation. **Figure 4** shows the simulation result for both 2µm and 5µm thick sensor electrode patch respectively. The maximum stress result for 2µm thick sensor electrode is 1764MPa while 5µm thick sensor electrode has a lower maximum stress of 1131MPa. This is negligible as only a single point on the electrode trace is of max stress. The majority stress experience along the trace is approximately at or less than 10MPa for both sensor electrode thickness. The strain analysis result is insignificant as shown in the result Figure 5.

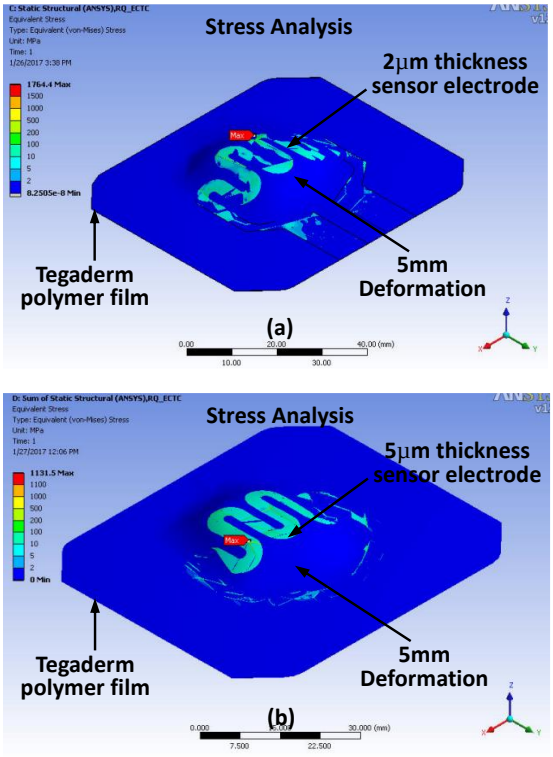

Figure 4. Stress simulation result (a) 2µm thick sensor electrode, (b) 5µm thick sensor electrode

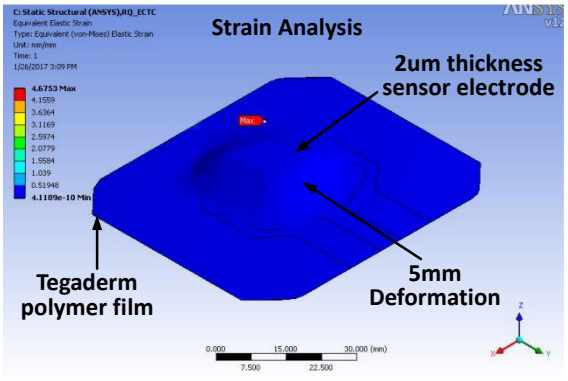

Figure 5. Strain simulation result for 2um thick sensor electrode

IV. FABRICATION OF SENSOR PATCH

Fabrication of sensor patch was illustrated in Figure 6.

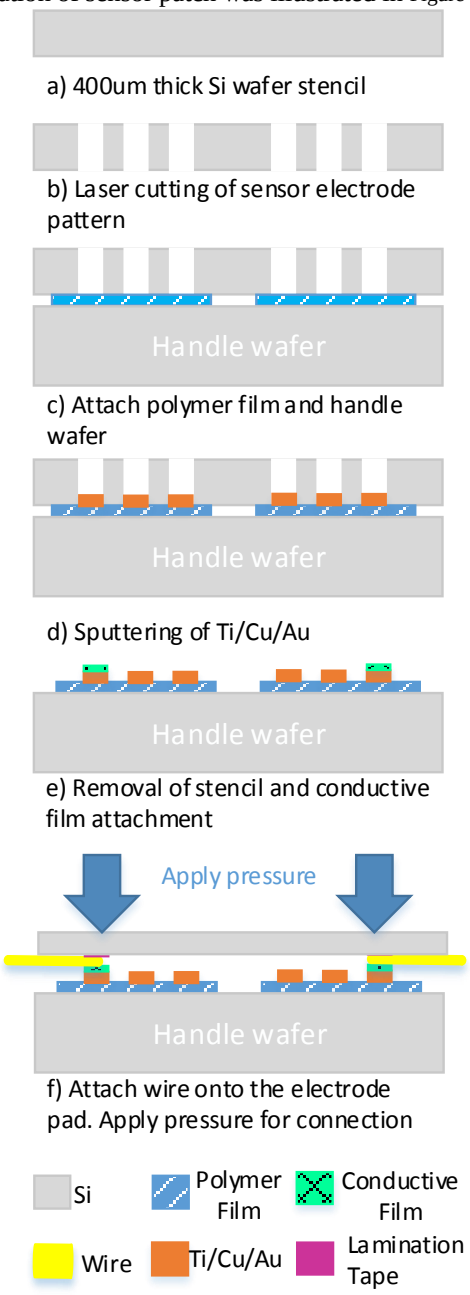

Figure 6. Fabrication process flow for sensor patch

The first step of the fabrication process is the stencil fabrication. The sensor electrode pattern is being laser machined onto a 400µm thick silicon wafer. The next step is to position and attach the polymer film onto the back of the stencil wafer with the aid of alignment marking on the stencil. A 700µm thick wafer is attached onto the back of the polymer film as a handling wafer. The device wafer undergoes sputtering process for the patterning of the sensor electrode and pad. The first layer of metal used is titanium metal with a thickness of 200Å. This titanium layer acts as

an adhesive layer between the second metal layer, copper and polymer film. After titanium layer had been sputtered, a layer of 2µm copper is being sputtering followed by a thin layer of gold with thickness 200 Å. This thin layer of gold acts as a passivation layer and prevent copper layer from oxidation.

After the completion of sputtering process, the next step is to attach wires onto the sensor electrode pads. The stencil is then removed from the sensor patch. Double-sided conductive film is manually attached onto the electrode pads. Enameled wire of ϕ100µm is placed onto the conductive film for the connection of the sensor electrode to the reader module. A lamination tape is then place over the enameled wire and the electrode pad for protection. A piece of metal sheet is placed over the senor patch and wires. A downward compression force is being applied to embed the wire into the electrode pad for electrical connection. After the wire attachment process has been completed, the sensor patches are removed from the handle wafer and ready for the characterization tests.

Figure 7. shows the fabricated sensor patches. There are two different sensor patch sizes. 3-inch sensor patch is to be used for adult. As children and infants have smaller hand and limb compared to adult, 3-inch sensor patch is not suitable for usage during the cannulation. The 3-inch sensor patch will be too big for adhesion on the hand/limb which will either affect the sensor electrode position on the cannula site or the electrode will be crumbled during the procedure. These will affect the electrode resistance to be unstable and inaccuracy in detecting skin swelling.

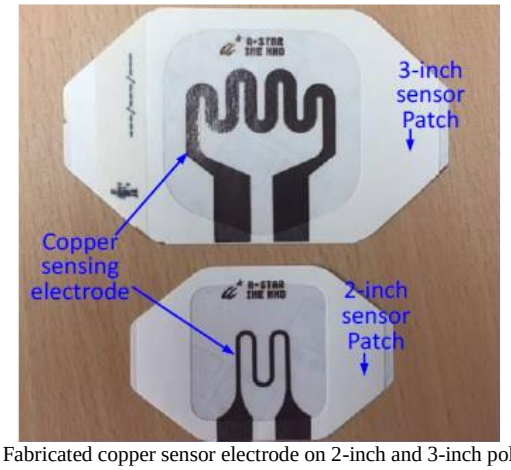

Figure 7. Fabricated copper sensor electrode on 2-inch and 3-inch polymer patch

V. Result and Discussion

A. Polymer Film Characterisation

A tensile pull test is performed on the polymer film to characterize the maximum tensile stress and strain at break point. The polymer film is tested using Instron Universal Testing machine 5569. Three samples of polymer films are used for this test. The polymer films were cut into 26mm in length by 10mm in width. The thickness of the polymer film is 30µm. Pneumatic side action grip with rubber face is used to grip the sample. The test rate was set at 50mm/min. the test result for the polymer film is shown in Figure 8.

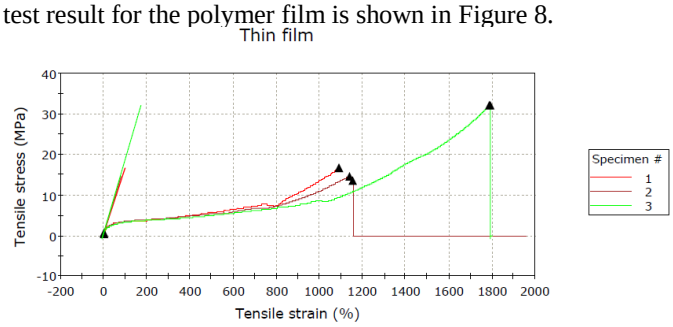

Figure 8. Polymer film tensile stress Vs strain result

The result indicated that the maximum tensile stress for the polymer film is 21.1 MPa with a standard deviation of 9.62 and stress at break point at 20.79 MPa. While the tensile strain of the polymer at break point is 1345.95% with a standard deviation of 383.19. The tensile stress and strain result are consolidated in TABLE II. TABLE III. This shows that the simulation result of the trace presented earlier is within the tensile stress at break point.

TABLE II. Tensile Stress Result For Polymer Film

Properties	***Mean Value (MPa)***	***Standard Deviation***
Maximum Tensile stress	21.13	9.62
Tensile stress at Yield (Offset 0.1 %)	0.59	0.4
Tensile stress at Break (Cursor)	20.79	9.87

TABLE III. Tensile Strain Result For Polymer Film

Properties	***Mean Value (%)***	***Standard Deviation***
Tensile strain at Yield (Offset 0.1 %)	2.84	0.41
Tensile strain at Break (Cursor)	1345.95	383.19

B. Ex-Vivo Test

The next characterization test film is the ex-vivo testing of the sensor patch. Figure 9. shows the block diagram for the ex-vivo setup. This test is performed on a pork knuckle. Main equipment used in the test setup are 3-Dimensional scanner, syringe pump and multimeter.

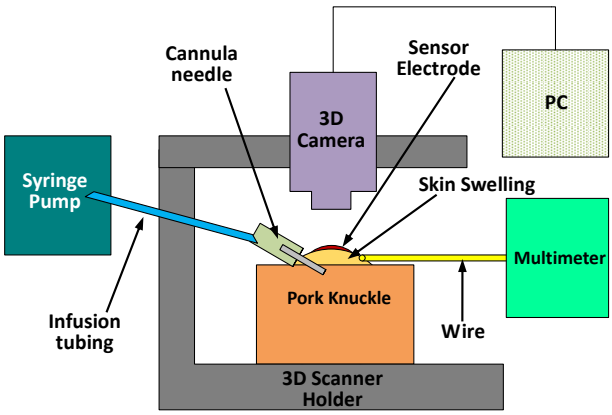

Figure 9. Ex-vivo test setup block diagram

The first step of the testing is pre-preparation of the pork knuckle. The pork knuckle tends to condense fluid on the skin surface under room temperature condition of 20deg C. The fluid condensation on the skin poses an issue for the adhesion of the sensor patch. The sensor patch will either unable to adhere conformably to the pork knuckle's skin surface or the sensor patch will delaminated during the characterization. This resulted in unstable and inaccuracy in the sensor patch measurement.

The next step is to prepare the syringe pump for the administration of the fluid. Food dye is mixed with water solution and filled into a 10ml syringe which is connected to the infusion. The color of the food dye acts as a contrast agent for better visibility under the pork knuckle's skin tissue. The syringe is inserted into the syringe pump and the infusion rate of the pump was set to 50ml/hr.

A 22 gauge cannula needle is then inserted into the pork knuckle subcutaneous tissue layer. The needle is then removed leaving the cannula tip in the tissue layer. The infusion tubing is then connected to the cannula for the administration of the food dye solution. The sensor patch is placed over the cannula for the skin swelling detection and to secure the cannula at the cannulation site. The sensor patch's output wires are connected to a multimeter for the measuring of the resistance change during the procedure.

The 3-dimensional scanning camera is placed onto a customized holder. This is used for scanning the surface of the pork knuckle and the measurement of the skin swelling bump height. An initial 3D scan of the set-up is required in order to have the reference point that will be used to measure the bump height during post processing. Micropore tape are placed on the sensor patch as markers for a better 3D scanning profile and easy of post processing.

Once the initial resistance value and the 3D scan profile of the setup has been measured by the multimeter and the camera respectively, the setup is now ready to perform the sensor patch characterization. The syringe pump will start to infuse the solution at rate 50ml/min till 6ml of solution infused. The resistance and bump height formation of the sensor patch will be measured at every 1ml of solution infused by the multimeter and the 3D scanning camera. The result of the bump height formation per 1ml of solution infused into the pork knuckle is shown in Figure 10. The result of the resistance value of the sensor patch is recorded and plotted in Figure 11. Based on the measurement result, the fabricated sensor patch can detect very small contrast volume of at least 2ml of in the subcutaneous tissue with a swelling bump height of 4mm.

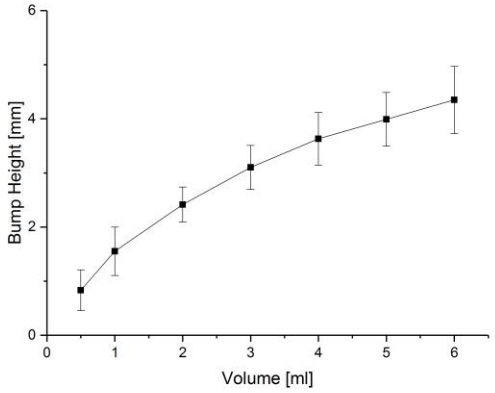

Figure 10. Bump height formation Vs infusion volume

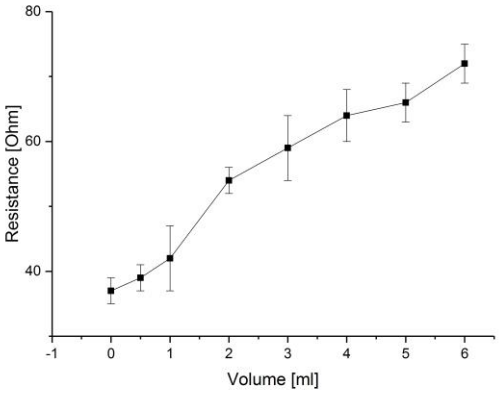

Figure 11. Resistance of sensor patch Vs Infusion volume

VI. CONCLUSION

In conclusion, some of the important results and significant achievements in this work are summarized as below:

1 A wearable and conformal sensor patch was developed for detection of skin swelling and tension.

2 Skin swelling or tension will cause the sensing electrodes of the patch to be stretched. A warning signal will be send to clinicians for immediate medical intervention

3 3D modeling and structural simulation analysis (deformation, stress and strain) of thin film metal (Ti/Cu/Au: 20 nm/ 2 µm /20 nm) with electrode pattern design were performed on the elastic polymer layer (30 µm thick).

4 Ex vivo testing shows that the sensor patch can detect skin tension and swelling (< 3mm deformation height) caused by 2-ml of fluid infusion. The sensitivity of the electrode sensor was (45% △R/ml).

The future work include characterization and optimization for this sensor patch using the in-vivo animal trial and human clinical trial.

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