Development of Coating Technology for Force-Feedback Application of Minimally Invasive Surgery

Wen-Cheng Kuo*, Yu-Chong Hu*, Tzu-Chien Wu*, Chine-Feng Wu*, Wei-Ching Wang** and Kuan-Chiao Cheng**

* National Kaohsiung University of Science and Technology
2 Jhuoyue Rd., Nanzih, Kaohsiung 811, Taiwan, rkuo@nkfust.edu.tw
** Metal Industries Research & Development Centre

ABSTRACT

This research is to develop the coating technology in order to meet the disinfection and sterilization requirement for the tools package of minimally invasive surgery. In this study, the parylene coating is applied to protect the sensors and tools during the EO Sterilization, high temperature high pressure sterilization and chemical liquid cleaning processes without effecting the sensitivity. Parylene film has good insulation and moisture, mildew, and acid corrosion resistance and other excellent properties. On smart instrument in minimally invasive surgery, parylene coating can achieve protection and disinfection resistance generated by electronic components for damage arising, reducing the probability of failure of surgical instruments and recycling the tools to avoid the use of disposable equipment, thereby reducing overhead costs. The coated system must also pass the pressure test to simulate the real surgery condition followed by the continuous sterilization processes. Test results show that by 5um, 10um thickness of parylene are suitable for disposable instruments, but also for the reuse of chip packaging devices.

Keywords: Parylene, Minimally Invasive Surgery, Force Feedback

1 INTRODUCTION

In the recent years, minimally invasive surgery must rely on the help of instuments. Many sensory input are lost due to the waterprof and insulation package. The vision has a lack of depth sensing and the tactual sensation is isolated. With the loss of tactual sensation, it could cause clamping slip, over excessive force which leads to the possibility of tissue removal or deedle puncture. In order to operate the instrument smoothly, it needs to be trained through hand-eye coordination [1].

During the minimally invasive surgery, the doctor opaterates the instruments only through vision. There is no actual quantitative value throughout the force process. With the development of the new clamping devices, the pressure sensor on them sends the force feedback by 1:1 and enables the doctor's hands that are operating sense the change tactilely. Therefore, the coating on the sensors is important to maintain the sensitivity. It must work under damp situations and withstand the pressure and the sterilization process [2].

Parylene film not only acts as a capsulation and a water-resistant coat, it has also been developed to be applied in areas such as MEMS, fuelcell and OLED. Parylene film has good insulation and moisture, mildew, and acid corrosion resistance and other excellent properties. It is used widely in applications such as semiconductors, sensors, medical equipments, architectural conservations and arsenal protection, etc. Parylene film has excellent mechanical and electrical properties, leading to lower dielectric constant.

There are currently many research on the use of parylene in biomedical applications. However, there are few research on the use of parylene on medical instruments, especially results of the sterilization and continuous cleaning processes [3]. As smart medical instuments advances, sensors and chips must be integrated. Parylene film can protect electronic components from being damaged by sterilization and continuous cleaning processes.

There are five experimental items for the research process: pressure test, chemical liquid cleaning (Plan A), chemical liquid cleaning (Plan B), high temperature high pressure sterilization and EO Sterilization. The initial design and the manufacture for the experiment used a dummy chip to deposit a 1um, 5um and 10um thickness of parylene. In order to find the suitable thickness of parylene coating, the parylene coating is tested under chemical liquid cleaning, repetition of pressure, high temperature high pressure sterilization and EO Sterilization. This is to see whether the parylene coating has been damaged and also if the resistance of dummy chip is affected.

2 METHODOLOGY

2.1 Dummy Chip Fabrication

For the conduct of the experiment, a dummy chip was created with metal conduction lines, and the size is the same as sensor. By using the dummy chip to replace the sensor for testing. Through the electrical current applied on these metal lines, the metal corresion can be examined for parylene film protection. The specification of the Dummy chip is displayed as figure 1. There are 69 pads on the chip, the dimension of each pad is 61x61 um^2, the spacing is 34um.

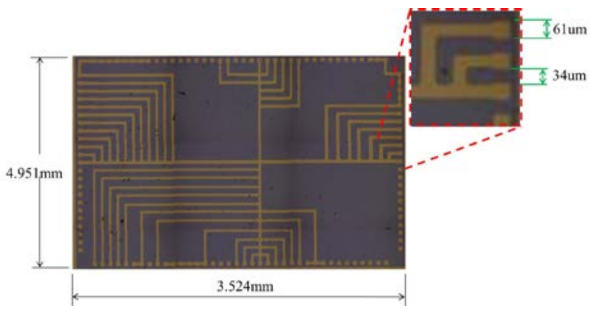

Figure 1: The specification of the dummy chip.

Figure 2 depicts the experimental setup. The dummy chip is used to replace the sensor, and glued the chip on the glass slide. Wire bonding is applied and the silver epoxy is used to connect the bonding wire and conduction wire (red). The resistance variation between the pads is measured to check the corrosion status.

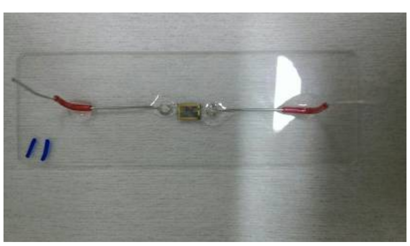

Figure 2: The actual dummy chip setup for testing.

2.2 Parylene Coating

The process of parylene deposition [4, 5] is shown in Figure 3. Parylene is deposited at room temperature at pressures of approximately 20 mTorr, with the mean free path of the molecules on the order of 0.1 cm. The deposition process begins by heating the solid dimer to 150 °C for vaporization. The vaporized dimer is then pyrolyzed to cleave the two methylene-methylene bonds and yield stable monomeric radicals (para-xylyene) at approximately 680 °C. The monomers are driven into the deposition chamber at room temperature by a pumping system, where they polymerize on the substrate. A cold trap (approximately -100 °C) is used to collect the unreacted monomers before they enter the pumping system.

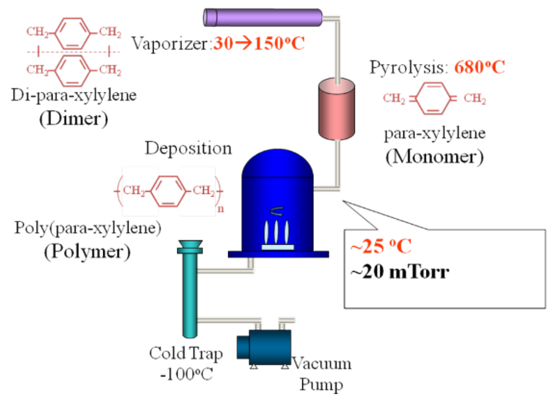

Figure 3: Schematic of parylene deposition process.

2.3 Parylene Coating Pressure Test

The setup of parylene coating pressure test is shown in figure 4. The 5Kg of weights is applied every 10 seconds for one hour. Based on the requirement, the pressure substrate holds the weights with a post is designed to attached to the imitation body tissue, and transmit the pressure to the underneath chip.

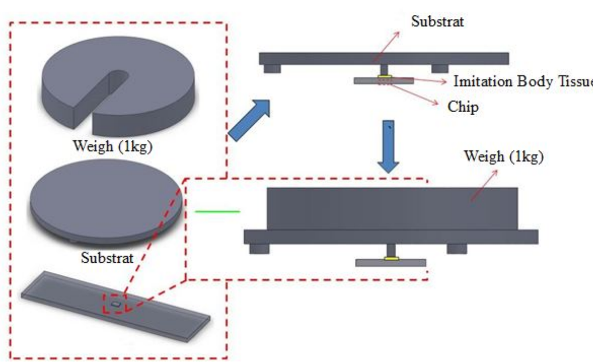

Figure 4: The setup of Parylene pressure test

2.4 Chemical Liquid Cleaning (Plan A & B) Test

For the chemical liquid (plan A & B) test, 1, 5, and 10um of parylene were deposited on the dummy chip respectively, following the Plan A process as shown in figure 5 and Plan B process in figure 6.

Figure 5: Chemical Liquid Cleaning: Plan A process

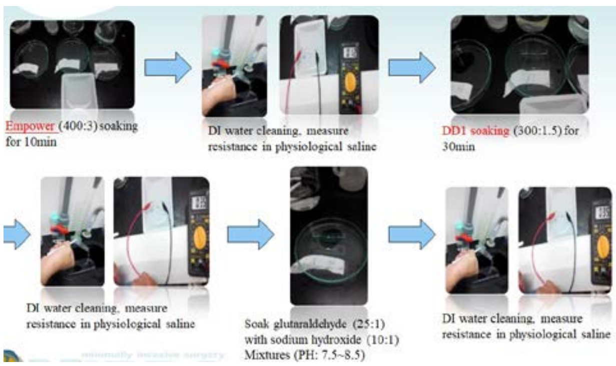

Figure 6: Chemical Liquid Cleaning-Plan B process

2.5 Parylene High Temperature High Pressure Test

The testing method requires placing the coated chip into a beaker and sealing it with aluminum foil. Then placing it in a EO sterilizer for 30 minutes at 120˚C to conduct the high temperature high pressure test as shown in figure 7.

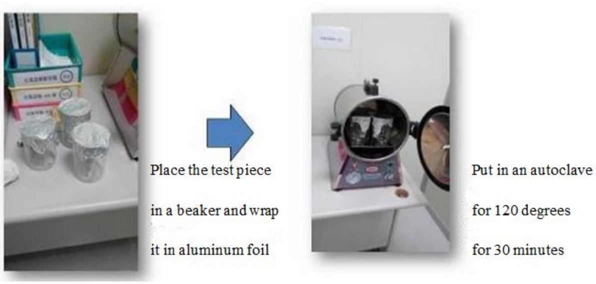

Figure 7: High Temperature High Pressure Test

2.6 EO Sterilization Test

For the EO Sterilization test, the thickness of 1, 5, and 10 um are deposited on the dummy chip separately, and then execute EO sterilization.

Table 1: the parameters for EO sterilization test

Autoclave Parameter Setting	**Setting values**	**Actual Values**
Sterilization pressure	240±20mmHg	239mmHg
Autoclave Temp	55±5℃	55℃
Autoclave Humidity	Above 50%RH	100%RH
leakage Pressure value	-500±30mmHg	-491mmHg
E.O. Pressure value	-390±20mmHg	-387mmHg
Sterilization Time	4.5hr	4.5hr
E.O. Concentration	500-700mg/L	623mg/L
wash frequency	10 times	10 times

3 RESULTS AND DISCUSSION

3.1 Pressure Test Results

Within one hour of the simulation operation, press once every ten seconds, measure the resistance once every ten minutes and measure a total of thirty times.

Table 2: Pressure Test Results

Resistance / Thickness	Untested resistance	Times of pressure test					Test Result
		1	5	10	20	30	
1um	0.032Ω	0.032Ω	0.033Ω	0.039Ω	0.059Ω	0.06Ω	Pass
5um	0.039Ω	0.038Ω	0.035Ω	0.08Ω	0.028Ω	0.017Ω	Passt
10um	0.008Ω	0.008Ω	0.008Ω	0.008Ω	0.008Ω	0.008Ω	Pass

After 30 times of pressure test, all the tests are pass. 1, 5, and 10 um of thickness coating can be used for medical device packaging.

3.2 Chemical Liquid (Plan A) Test Results

After cleaning the liquid, place it in physiological saline to measure the resistance. If the parylene film is damaged, the salt water will penetrate and cause the corrosion of the metal wire and the resistance value will not be measured.

Table 3: Chemical Liquid (Plan A) Test Results

Resistance / Thickness	Untested	5th	10th	15th	20th	30th	Test Result
1um	0.044Ω	0.012Ω	0.012Ω	0.012Ω	0.014Ω	0.043Ω	Pass
5um	0.279Ω	0.032Ω	0.07Ω	0.105Ω	0.021Ω	0.178Ω	Pass
10um	0.15Ω	0.013Ω	0.017Ω	0.017Ω	0.247Ω	0.024Ω	Pass

The high-grade disinfection of medical equipment endoscopes was performed on 30 repeated chemical liquid cleanings for different film thicknesses, showing that 1um, 5um, and 10um were not damaged, and both were suitable for non-disposable device packaging.

3.3 Chemical Liquid (Plan B) Test Results

After the chemical liquid cleaning, it is placed in saline solution to test the resistivity. If the coating is damaged, the saline solution will infiltrate and corrode the metal line causing the resistivity to be unmeasurable.

Table 4: Chemical Liquid (Plan B) Test Results

Resistance / Thickness	Unsoaked	Soaking liquid	5th	10th	15ht	20th	30th	Test Result
1um	0.044Ω	EM POWER	0.018Ω	0.066Ω	0.012Ω	0.013Ω	0.013Ω	Pass
		DD1	0.017Ω	0.05Ω	0.012Ω	0.013Ω	0.013Ω	
		Glutaraldehyde	0.035Ω	0.032Ω	0.012Ω	0.013Ω	0.013Ω	
5um	0.279Ω	EM POWER	0.048Ω	0.114Ω	0.048Ω	0.049Ω	0.05Ω	Pass
		DD1	0.055Ω	0.05Ω	0.048Ω	0.049Ω	0.05Ω	
		Glutaraldehyde	0.067Ω	0.064Ω	0.048Ω	0.049Ω	0.05Ω	
10um	0.15Ω	EM POWER	0.017Ω	0.023Ω	0.005Ω	0.005Ω	0.005Ω	Pass
		DD1	0.051Ω	0.013Ω	0.005Ω	0.005Ω	0.005Ω	
		Glutaraldehyde	0.035Ω	0.025Ω	0.005Ω	0.005Ω	0.005Ω	

3.4 High Temperature High Pressure Test Results

After the high temperature high pressure test, it is placed in saline solution to test the resistance. If the coating is damaged, the saline solution will infiltrate and corrode the metal line causing the resistivity to be unmeasurable.

Table 5: High Temperature High Pressure Test Results

Resistance / Thickness	No. of times						test result
	untested	5	10	15	20	30	
1um	0.013Ω	0.044Ω	0.0107Ω				On average 12 times, the resistance value is infinite
5um	0.345Ω	0.217Ω	0.065Ω	0.182Ω	0.051Ω	0.045Ω	pass
10um	0.051Ω	0.112Ω	0.073Ω	0.059Ω	0.815Ω	0.067Ω	pass

The film thickness of 1 micron is infinite when the resistance value of 12 times is measured. Therefore, the film thickness of 1 micron fails to pass the 30 times of sterilization test, and the film thicknesses of 5 and 10 micrometers pass 30 times of the sterilization test, these two thicknesses can be used in the packaging of non-disposable devices.

3.5 EO Sterilization Test Results

After EO Sterilization test, it is placed in saline solution to test the resistance. If the coating is damaged, the saline solution will infiltrate and corrode the metal line causing the resistance to be unmeasurable.

Table 6: EO Disinfection Test Results

Plan A			
Test Piece	1um	5um	10um
Unsterilization	0.019Ω	0.178Ω	0.024Ω
First EO Sterilization	0.029Ω	0.028Ω	0.141Ω
Plan B			
Test Piece	1um	5um	10um
Unsterilization	0.013Ω	0.05Ω	0.005Ω
First EO Sterilization	0.018Ω	0.264Ω	0.008Ω
Repeat 30 Times Pressure Test			
Test Piece	1um	10um	5um
Unsterilization	0.06Ω	0.017Ω	0.008Ω
First EO Sterilization	0.204Ω	0.008Ω	0.259Ω
EO Sterilization			
Test Piece	1um	5um	10um
Unsterilization	0.01Ω	0.009Ω	0.059Ω
First EO Sterilization	0.02Ω	0.018Ω	0.024Ω

According to the test results, the parylene film thicknesses of 1um, 5um, and 10um are suitable for single-use devices,

4 CONCLUSION

The traditional instruments for minimally invasive surgery do not integrate with sensors and chips. In the development of smart medical devices, water proof and resistance to repeated disinfection in order to protect electronic components are required. The instrument with pressure sensor on the clamped device can feedback the force to the doctor, so it shows the importance of the coating package, it needs to work in the humid environment, and it can resist the disinfection and sterilization and pressure resistance process to ensure the sensor can be normal.

According to the test results, 1um, 5um, and 10um thicknesses of the parylene film are suitable for single-use devices, and 5um and 10um can be used repeatedly up to 30 times according to the sterilization results. Therefore, these two thicknesses are suitable for repeated use of the device.

The topic of minimally invasive surgery is the key issue for future automation/robots to perform surgery, and the problem of circuit shortcut caused by erosion of the sensor by water/tissue fluid will be the key to the success.

This research is currently used for the force-sensing feedback mechanism of surgical instruments. In the future, it will be able to further expand the application of automated/robot maneuvering. At present, robots such as Da Vinci are still unable to give force feedback, so the development of parylene packaging technology will have more applications for smart biomedical devices.

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