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Micro Package of Short Term Wireless Implantable Microfabricated Systems

Leping Bu, Peng Cong*, Hung-I Kuo*, Xuesong Ye, and Wen Ko*

Abstract—Package is a critical part in biomedical implantable systems. Many factors affecting the host body and the life time of implantable systems need to be considered. Package becomes more critical for microfabricated systems with wireless charging and communication. This paper presents the first phase study on micro package techniques for short term (30 to 90 days) implantable systems. A MEMS implantable telemetry model system was designed for packaging evaluation. The transmitter was custom designed and fabricated using MOSIS processes and an external receiver was designed and built for data collection. For short term implantable systems, medical grade silicone outer coating is used for "tissue compatibility"; while multilayer polymeric and nanometer-thin metal or ceramic films were used for inner coatings to provide mechanical strength and to block vapor and moisture penetration. The total coating thickness is less than 0.6 mm. The electrical performances (leakage resistance) of test board and model devices coated with various package materials and processes are evaluated in 40 °C saline.

This paper presents: the model system; the evaluation methods and analysis of failure modes of polymeric coating on test boards; the solution to the failures and suggested coating techniques of polymeric materials; and the evaluation of model systems packaged with multi-layer coatings in 40 °C saline.

The expected performance of developed packaging method was verified by experiments. Implantable wireless MEMS system can be packaged with thin multilayer materials to have an expected life time greater than 30 days.

I. INTRODUCTION

THE micro fabricated implantable or attached monitoring and therapeutic systems are important research and clinical techniques for present and future health care. The bottlenecks impeding the implementation of micro-fabricated implantable systems are the package and power source of the systems. Present packaging of implantable systems uses bulk machining techniques and battery in which the package volume and weight are generally 2 to 50 times of the active components of a micro fabricated system [1-3]. This limits the usefulness of some implantable instruments. Furthermore, the cost and time for specialized industry to do the packaging are usually high and long. Individual research group may develop their own package techniques. However, these results are difficult to duplicate at other institutions.

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Implantable system package has remained to be an "art" like skill for some time. Recently, stimulated by the need for hermetic packages in food and aerospace industries as well as biomedical implant systems, many studies were made on the vapor permeability and biocompatibility of polymers, ceramic films, and the mixture of metal, organic and oxide films. Some reports on package for microfabricated biomedical devices have also published [4-9]. There is a need to integrate results from literature and to apply them for complete micro-package of functional biomedical implant systems.

The goal of our study is to develop the understanding and technology, to demonstrate the processes for micro-package of implantable devices, and to develop a micro-package technology platform for packaging of biomedical implantable systems and to document the techniques, so that it becomes a transferable, learnable skill. This paper summarizes results of the first phase study on micro-package of short tern implantable systems with a life time greater than 30 days.

The package of implantable systems has two functions: one is to protect the implant system from being damaged by the host and the next is to protect the tissue and body environment from being harmed or suffering undesirable effects from the implant. The considerations include: physical (mechanical, electrical, and thermal), chemical (water, O2, vapors, and ions), and biological effects [2-5]. To protect the implant system, the packaged should be: **i)** mechanically strong can isolate the device from undue stress, strain, and torsion; **ii)** hermetic or vapor impermeable to prevent water and vapors from permeating through; **iii)** biologically inert so that the tissue capsule growth around the package will not unduly alter the function/operation of the system. In order to protect the host body, the package should have **i)** an outer layer with a mechanical stiffness/softness similar to the surrounding tissue; **ii).** a smooth surface and rounded shape to avoid large stress and strain on the interface tissues, and no hot-spots; **iii).** all materials used are free from toxic components that may leak out to surrounding tissues; **iv).** be sterile, containing no biological elements (virus, proteins …) to cause pathological reactions around the implant site. The most commonly concerned requirements of implant packages are hermeticity or impermeability and toxicity. However, a biocompatible package should have all of these functions mentioned above.

In order to develop the micro-package technique for short term implantable devices in a biomedical instrumentation system, a model system was designed that represent typical wireless microfabricated implantable instrument. The

package surface and shape are carefully designed, and medical grade silicone outer coating is used for "tissue compatibility". Multilayer polymeric and nanometer thin metal or ceramic films were selected for inner coatings to give mechanical protection and to block vapor and moisture permeation. With these package designs, the major factor that limit the life time of implantable system is the vapor and moisture penetration through the package. The drop of leakage resistance and the change of device performance caused by low leakage resistance are used as the indication of pending failure. Figure 1 shows the laboratory setup used to evaluate packaging materials and packaged devices. The packaged device is immerged in 40°C saline, the RF signal from the device is received by the receiving coil and sent to the receiver, and the processed signal at the receiver output is recorded and observed from a scope or other display units.

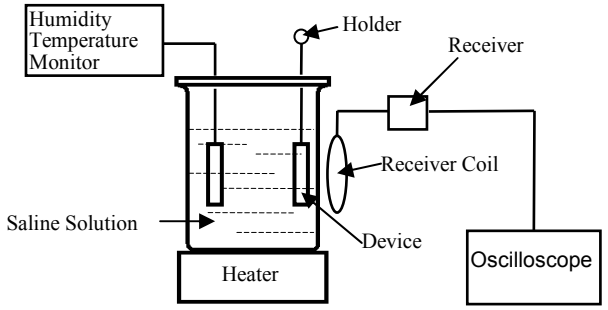


Fig. 1. Laboratory setup for package evaluation.

II. THE IMPLANT MODEL SYSTEM

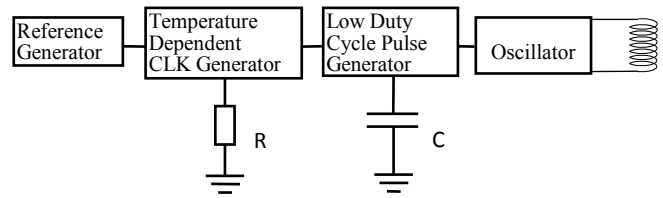
The implantable model system consists of: (A).The implantable telemetry transmitter unit that can sense changes of resistance, and capacitance in the package; and (B). The specially designed portable receiver that amplifies the RF signal and to process the signal for recording and display.

A. The Implantable Telemetry Unit

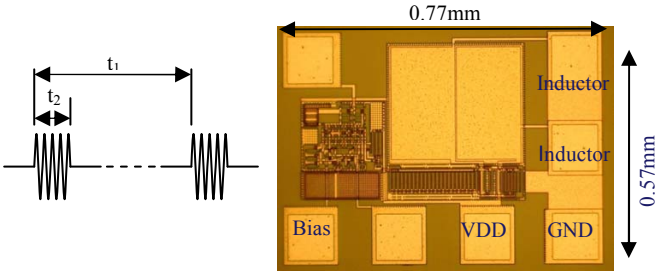
The main part of the implantable telemetry unit is a silicon integrated circuit chip. Figure 2 shows the functional block diagram, the output wave forms, and a microphotograph of the telemetry chip. The chip may operate from 100 to 400 MHz, consumes 0.7μA at 2.7 to 4 volts, and sends out low duty cycle RF pulses. The total current consumption, I, is sensitive to chip temperature, and the duration t_1 and t_2 are sensitive to the external resistance, R, and capacitance, C, respectively.

B. The Receiver

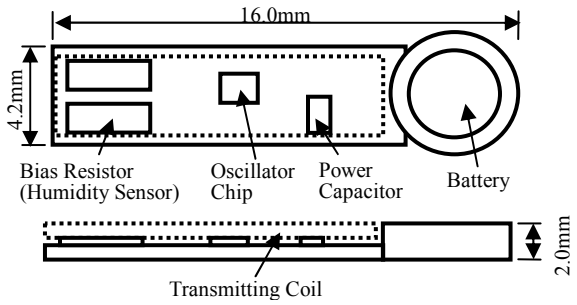
In order to conserve power, the RF signal of the telemetry Unit has a very small duration, t_1 (0.3 μS), very small duty cycle, and poor overall wave form. It is difficult for commercial RF receiver to track the signal. A special receiver unit was designed and tested to function properly. Figure 3 shows the input and output pulses wave forms of the receiver, and the functional block diagram of the receiver built on a 60mm x 45mm PC Board.



(a) Block diagram of the telemetry chip with external R and C

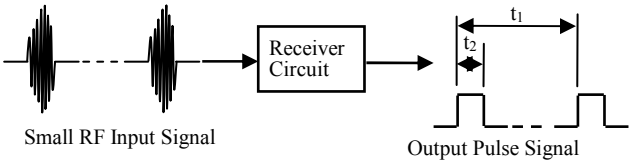


(b) Output RF pulses (c) Photograph of the telemetry chip

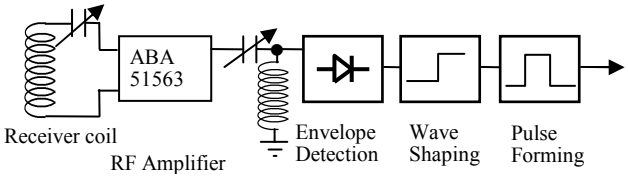


(d) The telemetry unit with antenna coil and external components

Fig. 2. The telemetry chip and the telemetry unit.



(a) Input and output wave forms of the receiver



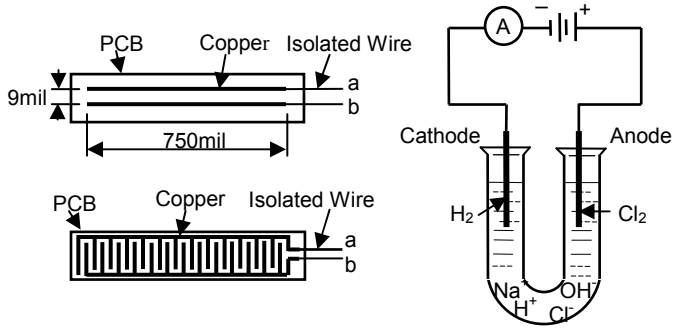
(b) Functional Block diagram of the receiver

Fig. 3. The RF receiver.

III. PACKAGING MATERIALS AND COATING TECHNIQUES

Many implantable telemetry units with battery were packaged by conventional dip coating with medical grade silicone as outer coating and ENCAP Epoxy as inner layer. They were tested in saline and failed in few hours to few days randomly, at the beginning of the project. A study on the failure modes and coating technique of polymeric

materials was made. Figure 4-a shows two types of PCB test boards with two closely spaced electrodes, 'a' and 'b', to be coated with polymeric packaging membranes with various thickness. The coated boards are immerged in 40°C saline solution, as shown in Figure 1. The time to fail were measured by monitoring the resistances between 'a' to 'b' and between 'a' or 'b' to an electrodes connected to saline solution. When any of these resistances is below 10^8 ohms, the unit is considered as failed.



(a) (b)

Fig. 4. (a)The test board for evaluation of polymeric membranes; (b)The chemical cell used to locate failed point.

The failed spots are generally very small and difficult to locate even under a microscope. A chemical electrolysis cell was used to locate the microscopic failed spots, as shown in Figure 4-b. If a DC voltage, such as 10V or 15V, is applied between any two of the leads [a, b] and saline electrode that showed low resistance, a small current will flow through the failed spots. The hydrogen bubbles may be observed at cathode leaking point. While at the anode leaking point copper is oxidized into Cu $(OH)_2$ which is a blue flocculent precipitate that can be observed. In this way we can locate the failed spot and determine the failure modes.

A. Coating Materials and failure modes

Based on previous package experience in our lab, several materials have been used for initial evaluation. They include: CTSR-12; EPO-TEK 353ND; ENCAP-FP4450, FP4451; M-COAT C KIT 6689; and MDX 4-4210, their properties can be found from the web sites [10]. Conventional cleaning, baking, and dip coating package methods were used for the first group of test boards. They failed from hours to days randomly. It is evidence that the performance of coating is determined not only by the material, but also by the process of coating and curing. Using the processes shown in Fig. 4-b, six failure modes were observed in the first group of test boards. They are: 1. Air bubble, 2. Foreign materials, 3. Crack, 4. Leakage from edges, 5. Hump, and 6. Sharp Corners, and uneven coating. Figure 5 and 6 illustrate the microscope photographs and explanation of these failure modes.

An improved coating method was evolved. The second group of test boards was packaged following the new coating procedures. They showed greatly improved results. All the single layer coated boards lasted more than 19 days. The 380 µm thick MDX4-4210 coated board lasted 38 days. Some boards coated with EBCAP as inner layer and MDX4 as outer layers are being tested. A few samples and their tested results are shown in Table I.

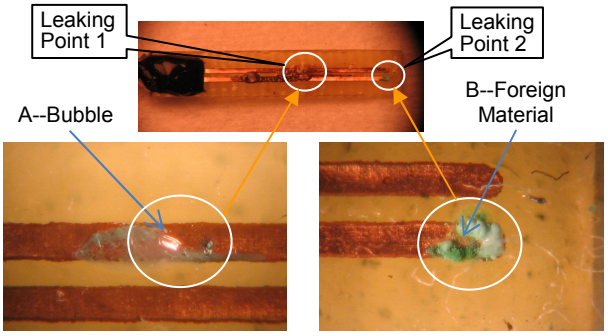
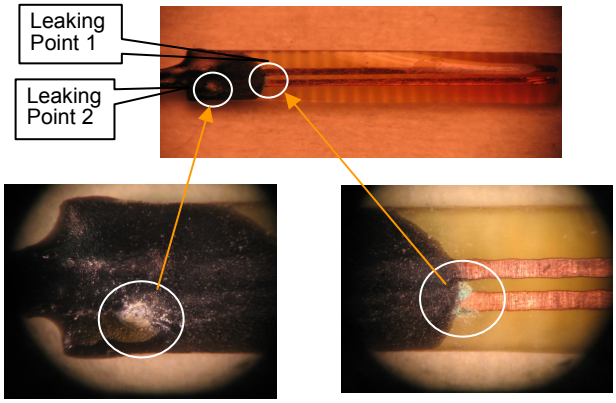
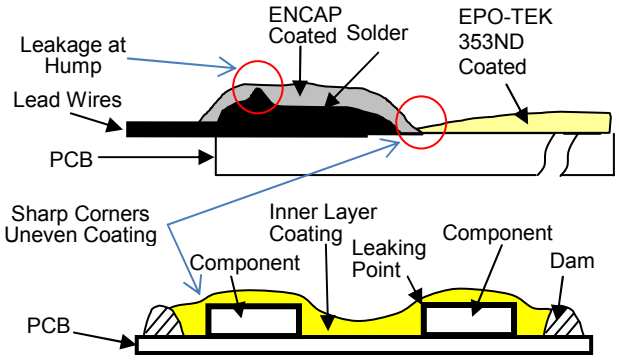


Fig. 5. An example of failure modes 1, bubble, and 2 thread dusts. Board #4 Coated with 27.5µm M-COAT C KIT 6689.



(a) The photographs showing the failed spots



(b) Explanation of the failure modes

Fig. 6. An example of failure mode #5.-hump and #6.-uneven coating.

TABLE I
TESTED MATERIALS AND RESULTS

Sample Number	Coated Material	Coated Thickness(μm)	Time Before Failure (hour/day)
#6	ENCAP	330.0	941/39
#7	M-COAT C KIT 6689	101.0	458/19
#8	MDX 4-4210	91.5	482/20
#9	MDX 4-4210	150.5	670/28
#10	MDX 4-4210	381.0	914/38

B. Recommended Coating Techniques

The coating method can be divided into dip coating and thin layer coating. For dip coating, it is hard to control the thickness and uniformity of coating layers. Any defect on the single layer would cause failure. For multiple thin layers coating, it is relatively easier to control the uniformity by using roller or other tools. The thickness of a coated layer can be controlled by the number of times the roller goes over the board with coating materials. Furthermore, defects on one layer would be covered and protected by other layers. The chance to have defects of multiple layers aligned at the same location is very small. Therefore, multi-layer coating is better than single dipping coating or single thin layer coating.

Based on the results on test boards, for short term implants the MDX 4 is selected for the outer layer coating material for biocompatibility; and the ENCAP is recommended for silicon ASIC Chip protection and the protective inner coating. The suggested coating processes are listed below:

1. Clean the surface of test board with alcohol (90%).
2. Dry the test board in 80 ^{o}C oven for 1 hour.
3. Mix the coating materials in a clean area carefully, and then put in a cold vacuum chamber to remove the bubbles.
4. Use a very small clean roller to coat the board uniformly with the material in thin uniform layers. Repeat coating several times with the roller to build up to a thickness of 50-100μm.
5. Put the coated PCB into a vacuum oven to partially cure the coating at a reduced temperature and time.
6. Repeat the steps 4 and 5 to build up coating to the final thickness, then completely cure the unit in a vacuum oven according to the instruction of the coating material.

The failure modes can be eliminated by careful handling and proper package design. Some suggestions are given below:

1. Bubble removal—Bubbles are generated during stirring and mixing. The mixed material should be put in a cool vacuum chamber to remove bubbles. Coated devices should be cured in a vacuum oven with controlled Temperature profile that increases slowly at the beginning.
2. Avoid dust and foreign materials—The mixing and coating should be processed in a cleaning room or hood.
3. Avoid solder hump—Use careful laboratory practice.
4. Protect the I.C. chips—If the electronic chips are assembled by wire bonding, the wire bonds should be secured by epoxy individually before packaging, to prevent the wires from pulled off due to the shrinkage of the coating material during curing. ENCAP epoxy is the common material used for first coating of silicon chips. Follow the ENCAP instruction to protect the chips before coating the telemetry unit. If the flip chip assembly is used, this process is not needed.
5. Use multiple layers coating of a material—Before curing, the coating material has low viscosity, and is hard to achieve uniform coating around components edges. The step coverage would be poor. Multilayer coating is the solution at the present. Use several thin coating and curing to cover the steps and corners around components.

IV. EVALUATION OF TELEMETRY UNIT

For long testing period, the battery of the implantable telemetry unit, as shown in Figure 2, is replaced with leads connected to external power supply. The assembled unit is coated with several thin layers of ENCAP to obtain a hard smooth surface first. Then a very thin (nano-meters) interlayer of gold film is sputtered over the unit before it is coated with MDX4, as illustrated in Figure 7. For comparison, some of the telemetry unit does not have the gold vapor barrier layer; MDX 4 was applied directly over the ENCAP inner layer. The coated material and thickness of two sample units are listed in Table II.

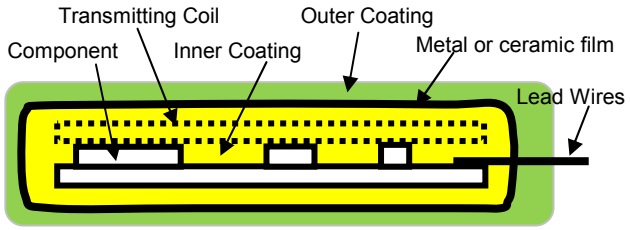


Fig. 7. Illustration of 3-layers-coated telemetry unit.

TABLE II
TESTED MATERIALS AND RESULTS

Unit No.	Coated Material	Functions	Coated Thickness (μm)	Time Before Failure (days)
#11	ENCAP Inner layer	Mechanical Support	200	**40days And continuing**
	MDX 4-4210 Out layer	Biocompatible Protection	150	
#12	ENCAP Inner layer	Mechanical support	200	**30days And continuing**
	Metal(Au) Middle layer	Vapor Barrier	0.30	
	MDX 4-4210 Outer layer	Biocompatible Protection	150	

The packaged telemetry unit was evaluated with the setup shown in Figure 1. The performance parameters that were recorded are: I — the DC current consumed; t_1—the period

of output pulses; t_2—the width of pulse; f —the RF transmitter frequency; V—the supply voltage. These parameters were recorded hourly or daily until the test is terminated. The termination criteria are: when any of the parameters changed 5 to 10% of the normal value. In this way the recovered transmitter can be cleaned and dried and is expected to be functional. Besides these performance parameters, the resistances from the power leads to saline solution were also monitored. The normal value is greater than 120 MΩ, when it drop to 20 MΩ the test would also be terminated.

In practice, the most important parameters are t_1 and I. If the quiescent current is I_0, the peak current during t_2 is I_P, then the average current, I, is equal to $\{I_o + I_p \times (t_2 / t_1)\}$. The smaller the t_1 and the larger the t_2, the lager the current I is. The normal current is about 0.7μA. When moisture penetrates the package, t_1 decrease and t_2 increases. The current increase quickly. A typical, I, and t_1 V.S. time curves of devices tested in 40oC saline is shown in Fig. 8. As the unit is lowered in saline solution there is a quick rise in current due to the RF loading of the saline solution. Then the current reach a stable value in 2 to 20 hours. The current is stable until near the termination time when the current increases and t_1 decreases rapidly.

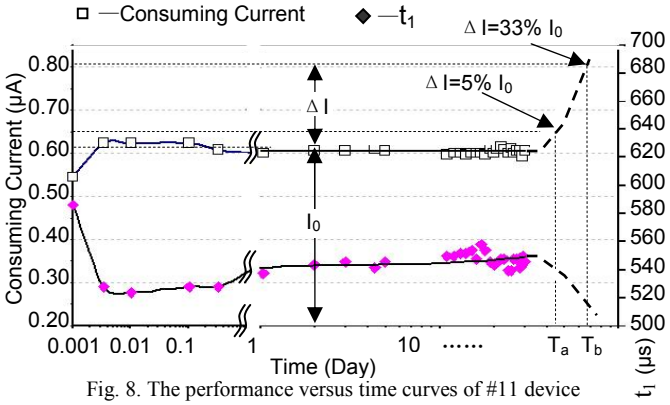


Fig. 8. The performance versus time curves of #11 device

A 4MHz RF recharging and control chip was designed, fabricated, and is being evaluated. This chip is used to charge the lithium battery and to turn the telemetry unit on and off with a code. Figure 9 shows the block diagram of the RF Chip.

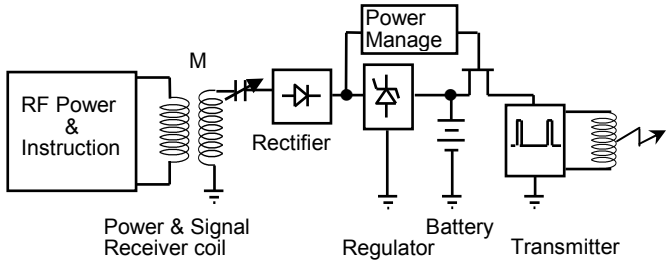


Fig. 9. The block diagram of the RF charging and control IC chip

V. CONCLUSION

Micropackage of implantable biomedical systems using multiple thin film layers of different materials was studied. The results of first phase micropackage for short term micro-fabricated implantable system are reported. The failure modes of coating polymeric materials on test boards were identified and analyzed. By using improved coating technique developed in this study, premature failures of packaged telemetry units can be avoid, thus achieves a life time greater than 30 days for the implantable model systems evaluated in 40°C saline. The total thickness of package layers can be less than 0.6 mm. The next study would be for micro-package of implantable systems with feed-through and communication windows for sensors and actuators. The final goal is to develop micropackage techniques for long term implantable biomedical systems with many years of implanted life time.

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