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INTERACTION OF ENVIRONMENTAL CONDITIONS: ROLE IN THE RELIABILITY OF ACTIVE IMPLANTABLE DEVICES*

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INTRODUCTION

Environmental conditions can have major influence on the lifetimes and reliability of active implantable medical devices (e.g., neurostimulators, cochlear implants, internal cardioverter defibrillators). These environmental conditions can range from those encountered by the device in processing and production to transportation and storage to actual operation. Although one might argue that the environmental conditions found in the first two situations are harsher than those of the third, failures that result from those situations are screened before implantation. If we assume that the active medical device is in perfect operational form at the time it is implanted, it will still experience a host of environmental conditions that can affect reliability. In fact, the ultimate goal of these medical devices is to restore the patient, wherever they may reside, to normal activities. A list of some environmental conditions that may be experienced by a device implanted in a representative patient is found in Table 1.

Although we know that this list is not comprehensive, it is extensive enough that we might recognize the challenge to engineer these devices for a myriad of conditions. That is accomplished, to a reasonable extent, by the manufacturers on a condition-by-condition basis through established standards testing. What has not been investigated to any degree is a systematic assessment into how these environmental conditions might interact to generate reliability issues that would not be present if the condition were isolated.

One condition that is not included in the table, but is explicitly understood, is that an active device must maintain hermetic integrity in order for normal operation of the device.

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TABLE 1. ENVIRONMENTAL CONDITIONS DURING OPERATION

Condition	Cause
Thermal	Hypothermic to febritic (35–40 °C)
Impact	Minor car accidents, trips and falls
Biochemical/humidity	Corrosive body fluids, including immune response
Electrical	Operational current and voltage
Mechanical Fatigue	Breathing, bending
Ionizing radiation	X-rays to cancer therapy
Electro-magnetic fields	Medical imaging to security screening
Pressure	Diving to climbing (300–50 kPa)

At the present time device hermeticity is secured by means of a welded titanium canister. The future in active implantables is to make devices very small and light weight. For example, designs for retinal implants include using a conformal coating (parylene) to form a moisture barrier between the active electronics and body fluids [1]. It is likely that future generations of other active devices will also have conformal coatings to reduce size and weight.

In this study we are developing a testbed for evaluating the reliability of active implantable devices under combined environmental conditions and with parylene as a barrier coating for active implantable applications.

EXPERIMENTAL SETUP

Table 1 provides some of the environmental conditions that could affect reliability of active implantable devices. Though neither extensive, nor comprehensive, this list contains too many variables to reasonably allow the contribution of each condition to be separated. For the purposes of this study we will limit the number of variables with which we begin the assessment to chemistry, voltage, current density, and geometry.

In order to assess these variables we will look for failures to occur in one of two ways. There will be either a change in the electrical measurements or a failure in the conformal coating. To enable the electrical measurements, we have designed simple passive microcircuits on a silicon chip. Each chip has four circuits with different geometries (Fig.1): two different line widths (10 µm and 50 µm), and one of each width is a direct line between bond pads, and the other two have multiple corners. This design was chosen to determine whether current density, voltage leakage, shorting, or stress concentration at the corners contributes in any way to reliability issues. For the initial test setup we have wire-bonded these chips to a ceramic chip carrier. Follow-up tests will use flexible substrates.

In order to detect whether the parylene coating fails we have seeded the surface of the test coupon with an easily traceable substance. A very thin (< 5 nm) layer of Ag was sputtered over the chip and carrier before it was vapor deposited with parylene (~17 µm thick). Using a mass spectrometer, we are able to easily detect the presence of Ag in the physiological solution down to 0.01 ppm. By sampling weekly we can determine whether the coating has been compromised. The initial integrity of the parylene in the presence of Ag does not appear to be adversely affected due to the thickness of the coating [2].

Each test coupon is wired to a power source and meter, and the coupon itself resides in a physiological solution. Eighteen coupons, wired in series, are tested at any given time. The current and voltage of the entire series is monitored for changes, with the ability to isolate individual coupons. Multiple test coupons in their individual physiological solution are maintained at 37 °C in a larger warm water bath (Fig. 2). We are testing three different chemistries at this time (Table 2) to mimic human body fluid and body fluid with the shown elevated levels of H_2O_2, and H_2O_2 and Cl^- to mimic a localized immune response. For each chemistry, six coupons are tested for statistical purposes.

DISCUSSION

Components and complete devices are challenged and pass tests and protocols designed to reveal their weaknesses in numerable conditions. Yet failures still occur in active implantable devices despite the extensive care taken by the manufacturers and the Food and Drug Administration to prevent them. One possibility is that these failures are the result not of an isolated condition, but rather of the interaction of more than one environmental condition.

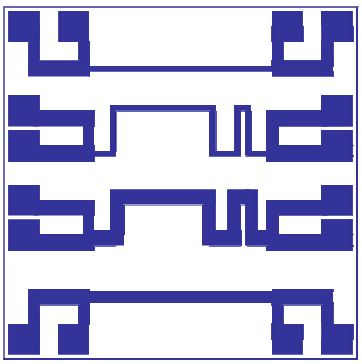

FIG. 1. DESIGN LAYOUT FOR THE TEST CHIP

To test the validity of this hypothesis, we have designed a test bed to evaluate four common conditions. By the very nature of these types of failures, these tests are designed to be long-term, with low failure rates. At the present time, no single set of test conditions has shown to be especially vulnerable. In the next generation of tests, we will include passive components on a flexible substrate and introduce low-amplitude mechanical fatigue.

REFERENCE

[1] Meyer, J.-U., Stieglitz, T., Scholz, O., Haberer, W., and Beutel, H., 2001, "High Density Interconnects and Flexible Hybrid Assemblies for Active Biomedical Implants," IEEE Transactions on Advanced Packaging, **24**, 366–374.

[2] Vaeth, K. M., and Jensen, K. F., 2000, "Transition Metals for Selective Chemical Vapor Deposition of Parylene-Based Polymers," Chemistry of Materials, **12**, 1305–1313.

TABLE 2. CHEMICAL COMPOSITION OF PHYSIOLOGICAL SOLUTION

	Concentration (mg/L)
$CaCl_2$	140
$MgSO_4$	98
KCl	400
KH_2PO_4	60
$NaHCO_3$	350
NaCl	8000
NaH_2PO_4	48
Glucose	1000
Amino Acids	870
B-vitamins	2
Choline chloride	1
D-calcium pantothenate	1
Folic Acid	1
H_2O_2	1
HOCl	0.003

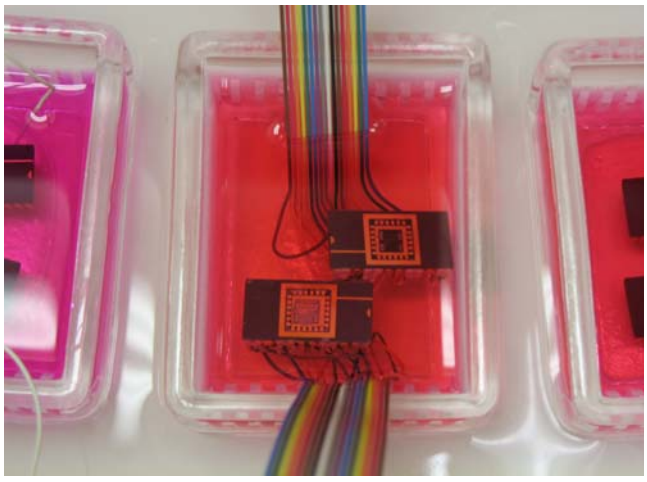

FIG. 2. IMAGE OF TEST COUPONS IN PHYSIOLOGICAL SOLUTION