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Protective multilayer packaging for long-term implantable medical devices

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ABSTRACT

State of the art packaging for implantable devices uses metal or glass housings that are reliable but limited from a miniaturisation viewpoint as well as cost-intensive. We suggest a hermetic and biocompatible thin film packaging based on alternating organic/inorganic coatings for further miniaturisation of smart implantable MEMS devices that can be applied for long-term implantation. The combination of high intrinsic molecular density silicon oxide (SiO_x) and pinhole-free and stress releasing poly-para-xylylene (parylene-C) thin films creates a new composite material, which is optimal for hermetic and biocompatible packaging. A novel single-chamber thin film deposition process was developed for the fabrication of SiO_x/parylene thin film multilayer structures, using a modified chemical vapour deposition (CVD) process. According to permeation and conformity aspects, the inorganic layer is the crucial layer of the coating. Permeation measurements the highly ceramic SiO_x material revealed a low helium gas permeation and a non-critical cracking thickness up to 300 nm. The morphology of the multilayer structure was analysed by scanning electron microscopy; an algorithm for defining ideal layer conformity was established and no local thickness deficiencies of deposited SiO_x layers could be observed. To evaluate the corrosion protection, an adapted calcium mirror test based on water droplet permeation was developed, and the water permeation of conventional parylene-C layers (4.5 μm) was compared to multilayer stacks composed of 3 SiO_x interlayers (4.7 μm).
In this paper, it could be shown that by tailoring the thickness ratio between the involved layers, the percolative pathway and thereby, the permeation for direct water exposure could be considerably reduced compared to conventional parylene-C single layers with the same thickness.

1. Introduction

Conventional biomedical long-term implants use metal and glass packaging to protect the human body from potentially non-biocompatible materials and on the other side, to protect the device from body fluids which can lead to its failure. For many biomedical implants, titanium is the material of choice due to its high biocompatibility and its mechanical properties [1]. Cardiac pacemakers for example, are usually packaged into welded titanium jackets. If implants have to communicate with an external reading unit, glass materials like Pyrex or Borofloat are used because of their RF transparency [2]. In addition, these materials have really low water vapour transmission rates (WVTRs). For metals and glasses, WVTRs of around 1×10^{-10} and 1×10^{-6} g mm m^{-2} day^{-1} respectively, were measured compared to polymeric materials which are in the range between 10 and 1×10^{-3} g mm m^{-2} day^{-1} [3]. Conventional encapsulation methods using metal and glass jackets generate large unused cavities between the enclosed MEMS device and the housing walls as shown in Fig. 1a. This condition limits the miniaturisation potential of the conventional encapsulation methods. In order to reduce these unused cavities, a conformal multilayer barrier structure in the μm-range as shown in Fig. 1b was developed. This barrier layer is able to coat the entire implant by a hermetic thin film [4].

In order to perform a conformal overgrowth on complex three-dimensional structures, plasma enhanced and standard chemical vapour deposition (PECVD, CVD resp.) processes were chosen to guarantee an uniform coating. For the creation of close-to-ideal tight thin film barriers, polymeric and ceramic materials were combined to form conformal multilayer barrier structures. The well-known polymer parylene-C was chosen due to its nearly stress-free deposition

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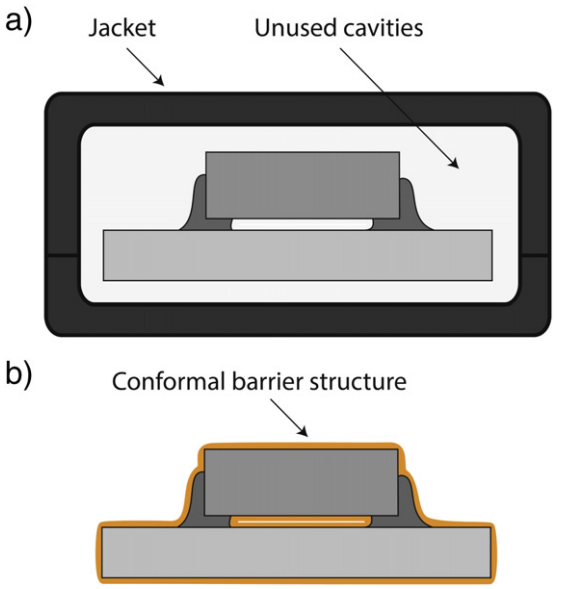

Fig. 1. Illustration of a conventional package using surrounding glass or metal jackets (a). A considerable decrease in packaging volume can be achieved by the novel thin-film layer encapsulation method for biomedical devices (b).

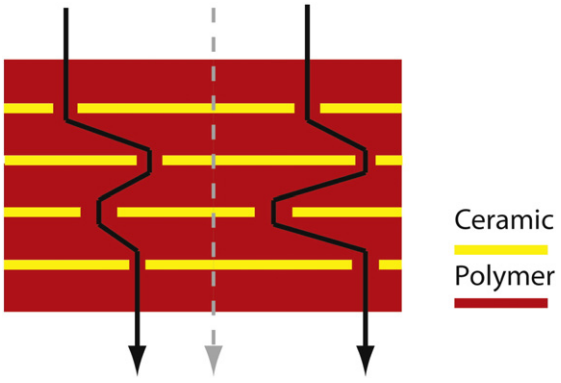

Fig. 2. A stack of polymeric pin-hole-free layers which exhibits a high permeation at molecular level combined with low-permeation but pin-hole affected layers leads to an increased effective percolative diffusion pathway.

property, pin-hole-free growth, excellent mechanical and chemical properties and high step-coverage [5]. However, the gap between the polymeric chains of parylene-C still allows a certain diffusion of atoms and molecules through the layer. In order to reduce this disadvantage, ceramic silicon oxide (SiO_x) layers are incorporated into the barrier film. Silicon oxide thin films are tight at the molecular level. However, they tend to increase internal stress formation of the multilayers which induces defect sites. If a silicon oxide layer is deposited on top of an elastic parylene-C layer, this subjacent polymeric material will act as a stress releasing layer. In addition, a stack of polymer and ceramic layers has the potential of combining the advantages of both materials in that the percolative pathway of permeates is increased as shown in Fig. 2.

The tight ceramic layer will allow diffusion only through its pinholes and cracks. Hence, the percolative pathway is significantly elongated compared to a homogenous diffusion that permeates the layer in a direct way.

2. Experimental

2.1. Material fabrication

In order to fabricate a multilayer coating composed of parylene-C and SiO_x thin films, a combination of a low-pressure chemical vapour deposition (LPCVD) reactor with a plasma enhanced chemical vapour deposition (PECVD) process was developed. An automation process was implemented, to guarantee the reproducibility as well as to control the key parameters of the different alternated depositions. Due to the high stability of process parameters by means of the automated deposition process, important properties of the protective barrier stack such as a conformal and uniform coating at low deposition temperature (<50 °C) could be achieved.

The deposition of parylene C was made by the use of a modified parylene coater (Comelec SA). Based on a conventional Gorham process [6], the parylene-C precursor is vaporised at a temperature of around 130 °C, decomposed to a monomer in the pyrolysis chamber at 650 °C and polymerised on the sample, placed into the deposition chamber at a total pressure of around 7×10^{-2} mbar. These process parameters were selected to obtain highly conformal and pinhole-free parylene layers [7]. The precursor dichloro[2.2]paracyclophane dimer (Galxyl C, Galentis Srl) also known as parylene-C was used [8].

To reduce the permeation of parylene based barrier coatings, an inorganic material consisting of SiO_x was chosen as the interlayer due to its high molecular density at low deposition temperatures and its reliable deposition technology [9,10]. The SiO_x thin-film layers are obtained by the dissociation of a hexamethyldisiloxane (HMDSO) precursor and additional oxygen gas molecules using an in-situ capacitively-coupled high-frequency plasma at 13.56 MHz. The SiO_x material, resulting from the binding of decomposed ions and radicals onto the substrate surface, is strongly dependent on the concentration of injected oxygen and HMDSO precursors into the deposition chamber. Moreover, the material composition depends on the residual gas pressure and the substrate temperature. In particular, the oxygen content of the SiO_x layer can be adjusted by variation of the O_2/HMDSO ratio. The O_2/HMDSO ratio allows a smooth adjustment of the barrier layer composition from purely inorganic, ceramic properties (SiO_2) with a maximum density, to layers having more polymer-like properties (SiO_x). This can be explained by the presence of organic groups mostly coming from the HMDSO precursor that are incorporated into the tetrahedral SiO_2 structure creating a reduced material density (for $x < 2$). The advantage of a purely ceramic SiO_2 composition is its hermeticity due to the high molecular density. However, these ceramic layers increase internal stress in the multilayer which might create cracks and pinholes within the deposited layer and thus, reduce hermeticity. The goal of the PECVD process optimization for SiO_x deposition is to reach the right balance between density/hermeticity and stiffness/internal stress of the SiO_x multilayer [11]. In this study, the barrier permeability in function of the layer thicknesses for a constant O_2/HMDSO ratio of 10 was investigated. This ratio showed in a prior investigation the optimal trade-off between stress formation and permeation to stack up the multilayer barriers [4].

To combine the parylene-C and the SiO_x layers in a multilayer, the process gases are injected into a single deposition chamber through automated valves which are alternatively opened or closed. In this study, 1 μm thick parylene-C layers were used, which correspond to a deposition time of 12 min. For the SiO_x barrier interlayers, the thicknesses of the deposited thin films were approximately 240 nm, obtained by a 5 min deposition time, an O_2/HMDSO flow rate that corresponds to a total chamber pressure of 14×10^{-2} mbar (3×10^{-2} mbar residual gas pressure), and a RF plasma power of 50 W. As a result, the chemical states present in the layer composition are dominated by the tetragonal binding configuration (≈70%) which can be considered as close to ideal

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