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Summary:
Medical devices often need some form of protection from their immediate environment. However, with small, complex, and sensitive components, the application of a protective coating is not a trivial matter This article discusses the problem and describes a solution.

The Thin Line: Gas-Phase Polymeric Coatings.

This column has dealt with coatings and surface treatments on several previous occasions. In some situations, surfaces that display specific biological characteristics are required. This is seen with the use of the biomimetic surfaces such as phospholipids.(l) In other cases it is a lack of biological reactivity that is the goal. The potential of diamond-like coatings (2) should be seen in this context. The characteristics of a coating for a medical device will naturally depend on many factors. In some cases it would be appropriate to use a hard, wear-resistant, inflexible coating; in others it would be helpful, even mandatory, if the surface had high flexibility and compliance. The increasing use of plastic materials in medical devices ranging from disposables to long-term implantables, and the wide range of functions required of those devices, has placed an increasing demand on coatings that could be used to protect them. This article addresses the issues that are involved and describes one of the materials that has emerged as a highly versatile polymeric coating material.

A resume of the types of device that may require protection in this way gives a guide to the specification of the coating material. At one end of the spectrum are the implantable electronic devices such as pacemakers and defibrillators. It is obvious that the electrical and electronic components of those devices require protection from the environment and it is usual to place all the components within a hermetically sealed titanium casing. However, the lead feed-through also needs protection and with many devices it is essential that the casing is electrically isolated from the surrounding tissue. Under these circumstances, a thin insulating coating is required that is free from defect and can be applied to all surfaces. It would also be useful if electronic circuits used in critical but non-implanted devices could be protected from the environment by a thin, highly conforming, insulating film.

There are a number of applications of sensors, transducers, and electrodes that are placed in or on the body in which protection is required and functionality and sensitivity must be retained.Ultrasonic transducers used intravascularly and blood-pressure sensors come into this category. The protective layer has to be applied in intimate contact with the small and complex shape, yet adding very little volume or thickness. Similarly, many of the fine electrodes used for nerve or other tissue stimulation may need to be selectively, insulated. On a slightly larger scale, many cannulae used in laparoscopic surgery are used for cautery, and require insulation on the metal conducting shaft.

Many devices are improved by coatings that are lubricious and a thin polymer layer that provides an extremely smooth and wettable surface would be beneficial. Examples here range from catheters to needles. By implication, when applied to devices coming into contact with tissues, those coatings should reduce corrosion or degradation rates and improve the host response to the device. A small number of implantable components have already been protected and enhanced in this way. However, if the potential applications are so widespread and the solution to so many problems as easy as applying a plastic coating to the surface, it is surprising that this is not a more widespread phenomenon. Indeed, it is interesting to note that thin polymeric protective coatings attract little attention when biomaterials and biocompatibility are described academically, and there is not a great deal more interest in the clinical and regulatory fields. One of the reasons for this is that the application of thin polymer films onto complex shapes is not easily achieved and there are few polymers able to be processed in this way. Conventional polymer processing routes are not always appropriate and the well-tried solvent casting and dipping techniques are variable in their output, with factors such as polymer thickness and structural perfection difficult to standardise. Furthermore, the protective layer must be free from defects because not only will a pinhole, scratch, or imperfect covering lead to loss of protection in that precise area, but also because defects can concentrate corrosive or degradative actions and have an effect far out of proportion to their size. With many polymer systems, it is not easy to prepare or maintain defect-free thin layers, especially when coating small, intricate devices of complex contour that are subjected to surgical handling and prolonged in vivo use.

It is only since the development of vapour deposition techniques that this intricate polymer coating has become feasible for many of those medical devices. The significance here is that most conventional polymer-coating processes involve the use of a liquid phase, which may be molten polymer or a polymer solution, where fluidity and surface tension conspire to make even, defect-free coatings difficult to achieve. As the name implies, vapour deposition, sometimes referred to as gas-phase deposition, involves conversion of the coating material into a gas; the direct condensation of the gas into a solid film gives much better results.

The principal advantage here lies in the fact that the polymer is deposited onto the substrate on a molecular basis; that is, molecules of the polymer condense individually onto the substrate. It is therefore easy to build up a layer slowly, controlling thickness and minimising curing or residual stresses. Because the gas phase can be homogenous and can penetrate into all surface features, it means that thin, uniform films are established on

even the most inaccessible parts, including many areas where surface tension would preclude access to liquids.

Perhaps the most intriguing question here is how the polymer is converted into a gaseous phase. Indeed, at first sight it would seem difficult to do this because organic polymers are not renowned for their ability to vaporize in a clean, uniform way and then be condensed back homogeneously into their solid form. Instead, most polymers burn and decompose on heating, which results in messy products. The secret lies in the technology that enables precursors of the polymer, rather than the solid polymer itself, to be delivered into the reaction zone. With the appropriate precursors and the optimal temperature, these substances are able to polymerize as they condense. The most obvious example would be to take a gaseous monomer, which would be drawn onto the substrate, usually with the aid of a vacuum, to spontaneously polymerize on deposition.

In practice, although a few polymer systems are able to be utilized in this technique, one material has recently come to the fore and is dominating the thin polymer coating of biomaterials. This polymer is poly(para-xylylene). It can be prepared by the polymerization of paraxylylene, but a better gas-phase deposition technique involves the use of the dimer di-para-xylylene, which is essentially two of the xylylene molecules joined together.

This is a white powder, which can be heated to approximately 150oC, at which point it will vaporize. This vapour can be passed into a chamber held at 650oC; under these conditions it pyrolyses, the dimer molecules splitting apart and forming reactive monomer units, which spontaneously polymerize on contact with any surface. Under the right flow conditions, the target substrate can be placed outside of the pyrolysis zone so that the deposition takes place at ambient temperatures; this is an important point with sensitive substrates and devices. It is necessary that any device that is to be coated should have reasonable vacuum tolerance and should not emit any significant amounts of volatile components under vacuum, because this could interfere with the polymer deposition.

This room-temperature gas-phase deposition of poly(para-xylylene) onto surfaces results in optically clear and chemically pure coatings that may be as thin as a few microns but are often approximately 25--µm thick and can give complete coverage to many complex medical devices. It would appear that the films have excellent barrier properties, good stability, and high dielectric strength.(3) Because the polymer is prepared from a single precursor and there is no requirement for any processing additive, there is no possibility of leachable impurities in the film. It is likely that there will be some residual dimer that does not pyrolyse, but by applying the techniques correctly, this is kept to a minimum and no problems of toxicity should arise.

Apart from the vacuum resistance mentioned above, there are a few limitations to the nature of the substrate. Some pretreatment may be necessary in the case of highly smooth and hard substrates to maximize adhesion, and certain elastomers require relatively thick layers to achieve maximum efficiency. Commercially, there are three forms of coating

available, each having slightly different properties and therefore different optimal applications. For example, one shows good tissue responses and low permeability and is most likely to be optimal for implantation. Another has good penetration into tubes and other inaccessible places. As noted earlier, there is little evidence of the overall biological performance of poly(para-xylylene) that is published and in the public domain and this point perhaps needs to be addressed. However, testing has been performed for regulatory purposes and drug and device master files exist in relation to such biological tests.

It may well be that other polymer systems can be utilized in this way, but the availability of poly(para-xylylene) has made it clear that the application of thin coherent protective films to medical devices is achievable and effective.

References

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