Temperature Moderated – Collision Mediated Coating of Polymer

Polymer coatings are important features of many class III medical devices. The premier example of a polymer coating in this space is drug-eluting coatings on cardiovascular stents. Implantable pacemakers are also covered with passive coatings of polymers such as parylene. In addition composite bioceramic-biopolymer coatings for hard tissue implants are being actively researched to solve issues such as delamination that can be an issue for plasma sprayed bioceramic coatings.

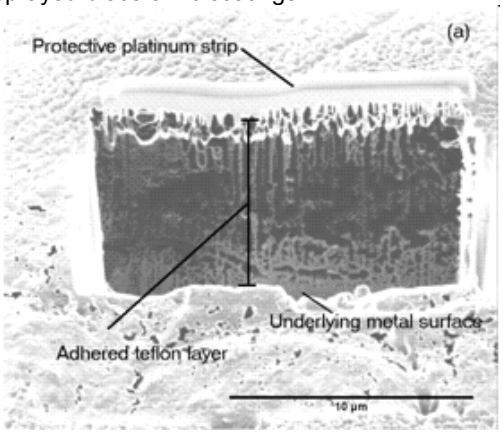

Fig. 1: A coating of PTFE on titanium applied by TM-CMC using ethanol as solvent imaged under a Focussed Ion Beam (FIB).

Polymer coating methodologies currently employed in the medical device space suffer from one or more defects that can be classified as biocompatibility or manufacturability issues. Sub-optimal drug loading and the use of cross-linking agents are examples of biocompatibility problems, while multi-step processing is a common manufacturability issue.

Coating	Polystyrene	PTFE
Solvent	water	ethanol / n-hexane
Precursor Flow (µl min)	100	100
Particle Size (nm)	200	300 - 3000

Table 1: Typical processing parameters for the TM – CMC process.

HKPB Scientific has developed a new coating technology termed Temperature Moderated – Collision Mediated Coating (TM – CMC). HKPB believes that TM - CMC has the potential to solve biocompatibility and manufacturability issues associated with polymer coatings onmedical devices. TM – CMC involves atomising a liquid based precursor coating composition to form an aerosol, which is directed to the surface of the substrate in conjunction with a stream of shot particles. The collision energy released by the impacting shot mediates the transformation of the precursor composition into a well-adhered coating and the liquid component of the precursor composition protects the therapeutic agent from degradation. The precursor composition can comprise polymer, solvent and therapeutic agents. No curing agents, cross linkers or other deleterious chemical agents are added to the precursor composition. The micrograph in fig. 1 and the X-ray Photoelectron Spectroscopy (XPS) spectrum of fig. 2 illustrate the efficacy of the process

HKPB believes that TM – CMC has many advantages which include:

- **Biocompatibility:** deleterious chemicals are not included in the precursor composition.
- **Biocompatibility:** therapeutics can be evenly distributed throughout the coating as polymer and therapeutics are concomitantly coated on the device.
- **Biocompatibility:** using TM – CMC the requirement for subsequent processing of the device is minimised reducing the opportunity for therapeutic degradation.
- **Manufacturability:** single-step process reduces processing time, labour costs etc.
- **Manufacturability:** a low flow rate of precursor composition ensures minimal waste of expensive therapeutic agents – table 1.
- **Manufacturability:** TM – CMC combines two existing equipment platforms, shot peeners and atomisers that are readily automated in a manufacturing setting.

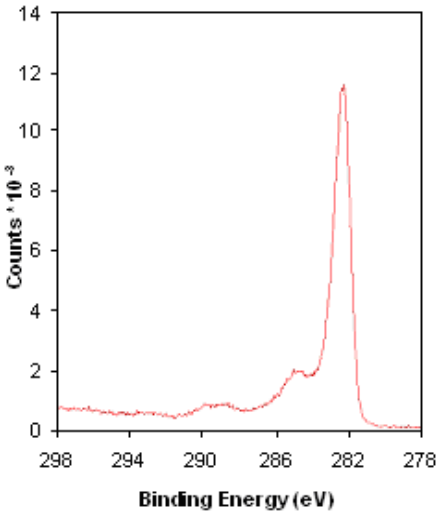

Fig. 2: A narrow region carbon 1s XPS spectrum of a polystyrene coating on 316 stainless steel applied by TM-CMC using water as solvent