

Method for Electrostatically Coating a Medical Device

Vipul Davé

Cordis Corporation, Warren, NJ 07059

Statement of Purpose: There are different methods to coat a medical device such as stents with polymers and therapeutic agents. Typically, the methods require dissolving the materials in a solvent prior to coating the substrate. Dissolving the coating material in a solvent may be undesirable due to environmental concern over volatile organic compounds. Electrostatically powder coating a substrate is relatively simple as it will process both low and high viscosity materials as long as they can be obtained in a powder form. The present study summarizes the application of electrostatic coating different materials onto substrates such as fibers and medical devices made from polymers and metals.

Methods: The selection of coating materials was based on a number of chemical and physical parameters. Physical parameters such as powder particle size (mean and distribution), density, melt viscosity, and electrical conductivity are amongst other important parameters that determine the powder deposition characteristics. Poly (caprolactone) [Tone 767], poly (ethylene oxide) [WSR-N-80], high density polyethylene GHR 8110 and hydroxypropyl cellulose (Klucel) were used as coating materials with particle size ranging from 60 to 200 mesh. Nylon 6, 6 and PTFE fibers were used as coating substrates. The powder coating process to coat a fibrous substrate is schematically shown in Figure 1. The fiber coating line consists of a feed spool, grounding unit, electrostatic powder coater, oven and take-up winder. A layer of polymer powder is fluidized by air that is charged negatively in the plenum of the coater. The powder coating variables that could have an impact on the amount of coating are bed fluidization flow rate (ft^3/h), electrostatic voltage (kilovolts, kV) and line speed (meters per minute). The furnace temperature was determined for specific process conditions and materials for uniform polymer fusion and bonding to the fibers.

Results:

Nylon 6,6 Multi-filaments/Poly(ethylene oxide): PEO was used to coat a nylon 6,6 multi-filament structure comprising 210 filaments, each having a denier of 3, at an oven temperature of 237°C . Figure 2 shows the amount of PEO coated on the nylon filaments as a function of electrostatic voltage and flow rate at 10 m/min and 20 m/min line speeds. Regardless of the line speed, the coating amount is very sensitive to bed flow rate as higher coating amounts are observed with increasing flow rates. There is a saturation voltage beyond which value there is a drop in the coating amount on the filaments.

PTFE Monofilament/Poly(ethylene oxide): PTFE monofilament was coated with PEO to increase the coefficient of friction. PTFE monofilament was generally rectangular in transverse cross-section, with a width of about 2-3 mm and a thickness of about 0.08 – 0.13 mm. The oven temperature was 320°C at a line speed of 27 m/min. Figure 3 shows the coating amount of PEO on the PTFE monofilament tape. It was observed that beyond 20

kV voltage the coating amount dropped. This shows that the trend of coating amount versus voltage is independent of substrate geometry i.e., cylindrical (nylon fibers) versus flat (PTFE tape).

Selection of Polymer Powders Based on Aeration: In order to understand powder aeration quantitatively, experiments were carried out on powders to obtain their bulk and tapped densities. The differential densities (fused density – tapped density) of the polymer particles were plotted (log-log) as a function of mean particle size (in microns) as shown in Figure 4. The data can be used as a guide in selecting powders for fluidized-bed coating applications.

Conclusions: A method for coating polymer powders on a substrate has been developed. Bed fluidization flow rate has a dominant effect on coating amounts. All powders acquired charge readily. However, some powders experienced difficulty in being aerated due to particle size, density and shape.

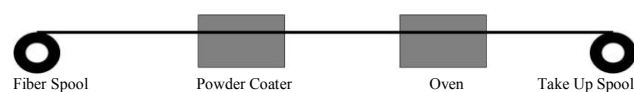


Figure 1. Electrostatic Powder Coating Process For Fibers

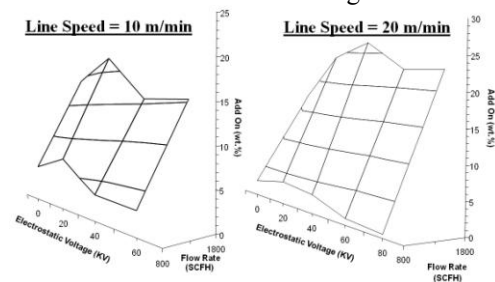


Figure 2. PEO Coating On Nylon 6,6 Multi-filaments

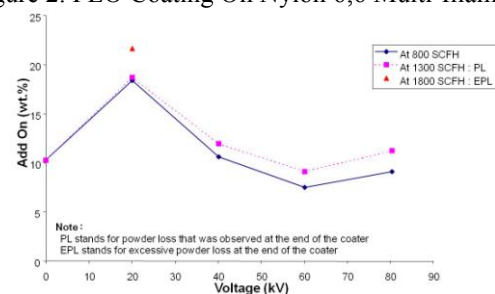


Figure 3. PEO Coating On PTFE Monofilament

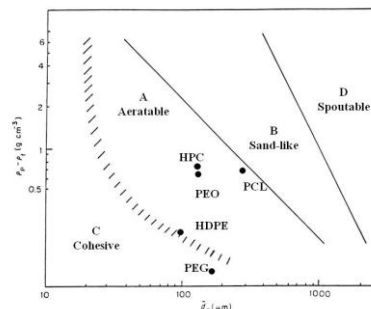


Figure 4. Differential Density Versus Mean Particle Size