Aqueous-Based Lubricious Coating Technology

Another option for manufacturers

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Patient comfort and cost savings have stimulated the quest for lubricious surfaces on invasive devices. This article describes an aqueous-based coating technology that may prove more successful than traditional methods that use organic solvents as well as the benefits for devices such as catheters and guidewires. Its implications for drug delivery are also discussed.

medical device technology

Reducing friction to gain market advantage

Devices used in the medical and dental industry are prepared from plastics, metals and ceramics that are often hydrophobic, non-slippery and/or non-biocompatible. High-friction properties are unfortunate because these devices should exhibit low-friction surfaces to facilitate insertion and manoeuvrability within blood vessels and other body conduits during certain procedures. Pressure from the insurance industry to reduce patient trauma, that is, to reduce the length of hospital stays, encourages device manufacturers to ensure that their catheters, guidewires and other invasive devices have low-friction surfaces. Device manufacturers often enjoy a market advantage if their devices exhibit low-friction profiles. In today's competitive market, a device with a coating that gives it additional advantages, such as improved biocompatibility, infection control and/or controlled release of bioactive compounds, is especially appealing.

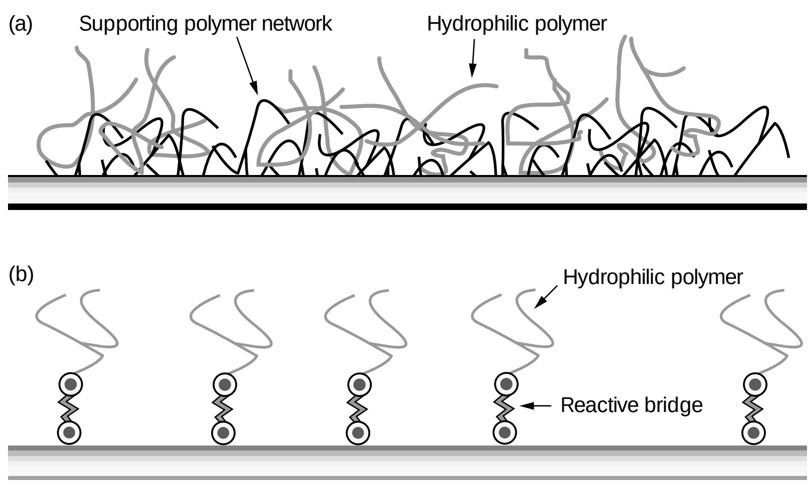

Figure 1: Two methods of coating hydrophobic surfaces with hydrophilic polymers, (a) establishing an interpenetrating network and (b) grafting one end of a functionalized hydrophilic polymer to the substrate.

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Current lubricious-coating technologies

Device surfaces are often coated with low-friction materials, such as polytetrafluoroethylene (PTFE), glycerin or silicone fluid, to render the surface slippery. Unfortunately, these hydrophobic polymer coatings often make the devices difficult for the physician to manipulate. Silicone fluids and glycerin are greasy and sticky, and PTFE coatings are slippery even when dry. In addition, the use of PTFE coatings is restricted because of their stiffness and poor bonding, and the limited supply of medical-grade raw materials that is available. PTFE, glycerin and silicone fluid are also unable to incorporate drugs or other bioactive agents. A "slippery when wet," hydrogel-like surface that is easily handled when dry, has the ability to incorporate a bioactive-compound and exhibits low bacterial adhesion is, therefore, desirable.

Finding the right technique

The technology for coating hydrophobic surfaces with hydrophilic polymers or hydrogels that hydrate and become slippery when wet is available. Unfortunately, when hydrated, hydrophilic polymer coatings have little physical integrity because of their high water content. A considerable amount of research has been conducted to improve the durability and substrate adhesion of hydrophilic coatings.

A common approach is to physically anchor a long-chain hydrophilic polymer in a supporting polymer network that is normally non-swellable in water. Conceivably, one end of the long hydrophilic polymer becomes entwined within the supporting polymer. The free end is able to become hydrated. This is known as an "interpenetrating network" (IPN) and is characteristic of many commercially available lubricious coatings. A schematic diagram is shown in Figure 1(a). Generally, the hydrophilic polymer is dissolved in an organic solvent together with the polymer that will form the supporting matrix. The device is coated with the solution and the solvent is allowed to dry.

Another approach is to graft one end of a functionalized hydrophilic polymer to the substrate. This is often accomplished via a reactive bridge between the inert substrate surface and a functional group on the hydrophilic polymer, see Figure 1(b). This results in a thin hydrophilic layer that is chemically linked to the surface.

These approaches begin to overcome many of the inherent limitations of hydrophilic coatings, such as limited wet strength, poor adhesion and fragility. Unfortunately, they are still inadequate because they tend to rely on cumbersome processing techniques, such as UV curing or organic-solvent handling. Given the current regulatory climate, many companies wish to avoid the use of organic solvents to eliminate the possibility of residual solvents in the device, reduce potential employee liabilities and/or minimize processing, waste handling and hazardous-material reporting costs.

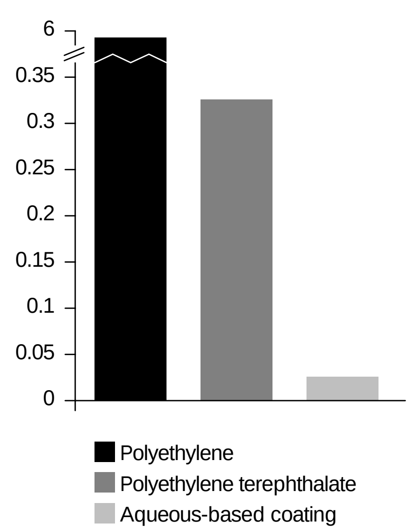

Figure 2: Coefficients of friction of an aqueous-based coating, polyethylene and polyethylene terephthalate.

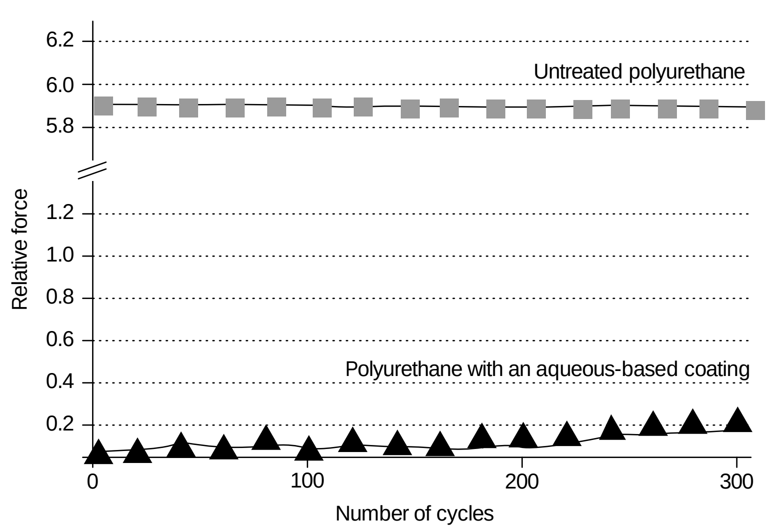

Figure 3: Durability of an aqueous-based coating in push–pull tests.

Aqueous-based lubricious coatings

A new lubricious coating was recently introduced that overcomes many of the physical and processing limitations of current hydrophilic coatings. The technology uses a simple, aqueous-based process that produces a superior IPN-type lubricious coating that is slippery only when it is wet. The coating consists of a chemically cross-linked supporting polymer network with long-chain hydrophilic molecules intertwined within it. The lubricity of the coating is shown in Figure 2. Poly(vinylpyrrolidone) is a commonly used hydrophilic molecule. The supporting polymer network possesses superior cohesive properties because it is cross-linked and not merely dried on to the surface. Therefore, it will not be eroded from the surface under relatively mild conditions as readily as polymers deposited by simple evaporation, see Figure 3.

The hydrophilic molecule is blended with an aqueous polymer dispersion. A cross-linking agent that cross-links the supporting polymer matrix is added to enhance coating integrity. This cross-linker can cure at room temperature. However, it is best to cure at about 60 °C to quicken the reaction and achieve the strongest supporting network. The process is simple and readily applicable to most coating facilities, see Figure 4.

Unlike coatings that use organic solvents, see Figure 5, there is no need to capture and dispose of hazardous materials. Eliminating organic solvents gives manufacturers the ability to incorporate bioactive ingredients that are incompatible with organic solvents or that could be degraded on exposure to them. Another advantage of using an aqueous base is the elimination of residual organic solvents that can compromise the safety of the device. In the United States, reporting requirements are reduced because there is no possibility that a company will exceed Federal environmental regulations or even state-specific reporting limits, such as the Massachusetts' Toxic Use Reduction Act and California's Clean Air Act. Regulatory requirements in the European community discourage the use of solvents and thus aqueous processing is preferred. Elimination of organic solvents is a proactive business decision because it can reduce a company's exposure to worker health and safety concerns. Increasingly, products that are produced using "green technology" are seen as having a market advantage.

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Preparing samples for processing.

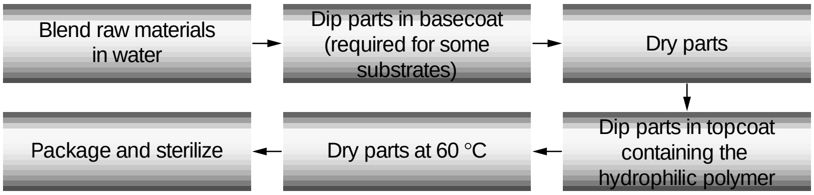

Figure 4: Flow diagram of the aqueous-based lubricious coating process.

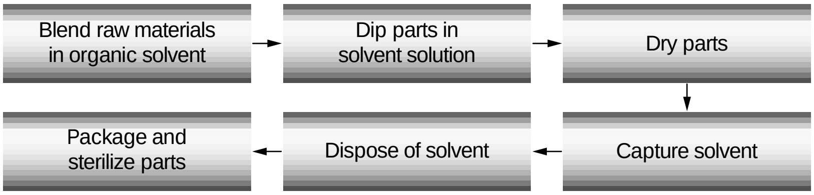

Figure 5: Flow diagram of the solvent-based lubricious coating process.

Table I: Substrates coated with an aqueous-based lubricious coating.

Polyethylene (HDPE and LDPE)
Polyurethane
Polyimide
Nylon
PEBAX
Silicone
Stainless steel (various alloys)
Nitinol
Aluminium
Platinum
Gold

Versatility

Compatibility. Perhaps the most important attribute of aqueous-based systems is their compatibility with nearly all medical materials. Table I provides a list of substrates that have been successfully coated with aqueous formulations and experienced no change in their underlying properties or shape. Sensitive crystallized polyurethanes do not "relax" because there is no solvent to attack the microstructure and, therefore, their size and shape remain constant. Aqueous-based lubricious coatings can be applied to the outer surface and to the lumen of tubing as small as 2.3 mm. They can be applied to complex geometries and thin wires, and to springs with minimal bridging.

Varied properties. Aqueous-based systems offer flexibility in formulation. By varying the chemistries and "recipes," different coating properties can be enhanced. For example, balloons and guidewires require the coating to be very flexible and resilient, and introducer sheaths and stents require a lubricious coating that is extremely durable. By modifying the supporting polymer network, these different specifications can be accommodated.

Drug delivery. Another important property of aqueous-based lubricious coatings is their ability to incorporate bioactive agents that are released in vivo. The coatings have the potential for use in drug-delivery devices and therapeutic intervention. This property has been demonstrated with the incorporation of silver oxide into the coating. Zone of inhibition studies demonstrated that there was antimicrobial activity on the surface, even after 30 days of soaking in artificial urine. Unlike conventional antimicrobial coatings, which initially show a huge spike of activity that rapidly dissipates, aqueous-based coatings maintain their activity at constant levels, see Figures 6 and 7.

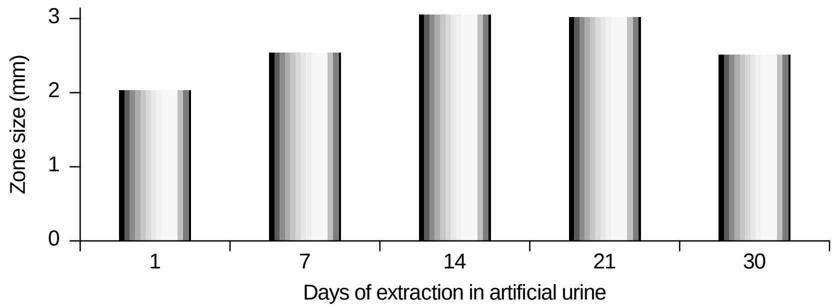

Figure 6: Zone of inhibition tests on the aqueous-based lubricious coating.

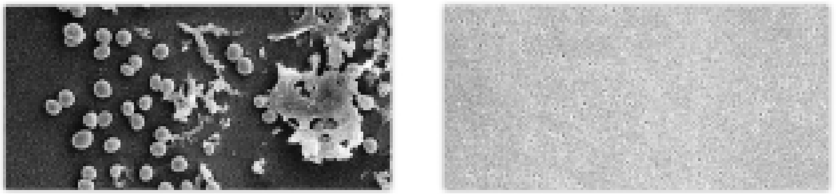

Figure 7: Bacterial adherence photographs of aqueous-based hydrophillic coating with incorporated antimicrobial agents.

Biocompatibility. Hydrogels, by their chemistry, imply biocom patibility and haemocompatibility. To evaluate this biocompatibility, a number of tests have been performed and successfully passed, see Table II.

Increased choice for manufacturers

Lubricious coatings have been a topic of interest for some time. Several physicians have stated that once they become accustomed to handling lubricious surfaces, they do not wish to use anything else. Medical device manufacturers, when attempting to meet market need for a lubricious coating, have a number of choices. If they have the internal resources, one option may be to develop a proprietary, in-house coating. If that option is either technically or economically unjustifiable, device manufacturers can avail themselves of the various coatings on the market. Each has its own set of disadvantages and advantages. Lubricious coatings offer excellent wet-friction reduction properties, high durability and gentle processing techniques, which make them an attractive option for many manufacturers.

Table II: Biocompatibility tests.

Direct haemolysis
System toxicity
Cytotoxicity
Sensitization test in guinea pigs
Acute intracutaneous reactivity
Pyrogen material mediated test
In vivo thrombogenic resistance study
Complement activation study
Coagulation study

Recommended reading

For an overview of lubricious polymers and the test methods associated with them, please refer to Yoshito Ikada and Yoshikimi Uyama, “Lubricating Polymer Surfaces,” Technomic Publishing Co. Inc., Lancaster, Pennsylvania, USA. ●

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