**3-Functionability:**

The functionability of a medical device depends on the ability of the material to be shaped to suit a particular function. The material must therefore be able to be shaped economically using engineering fabrication processes. The success of the coronary artery stent - which has been considered the most widely used medical device — can be attributed to the efficient fabrication process of stainless steel from heat treatment to cold working to improve its durability.

**4 -Manufacturability:**

It is often said that there are many candidate materials that are biocompatible. However it is often the last step, the manufacturability of the material, that hinders the actual production of the medical device.

**Performance of Biomaterials:**

The success of biomaterials in the body depends on factors such as the material properties, design, and biocompatibility of the material used, as well as other factors not under the control of the engineer, including the technique used by the surgeon, the health and condition of the patient, and the activities of the patient. If we can assign a numerical value *f*  to the probability of failure of an implant, then the reliability can be expressed as:

*r = 1 − f*

If, as is usually the case, there are multiple modes of failure, the total reliability rt is given by the product of the individual reliabilities *r1 = (1 − f1)*, etc.

*rt = r1 · r2 · · · rn*

Consequently, even if one failure mode such as implant fracture is perfectly controlled so that the corresponding reliability is unity, other failure modes such as infection could severely limit the utility represented by the total reliability of the implant. One mode of failure which can occur in a biomaterial, but not in engineering materials used in other contexts, is an attack by the body’s immune system on the implant.

Another such failure mode is an unwanted effect of the implant upon the body; for example, toxicity, inducing allergic reactions, or causing cancer.

**Surface Modifications for Improving Biocompatability:**

Prevention of thrombus formation is important in clinical applications where blood is in contact such as hemodialysis membranes and tubes, artificial heart and heart–lung machines, prosthetic valves, and artificial vascular grafts. In spite of the use of anticoagulants, considerable platelet deposition and thrombus formation take place on the artificial surfaces.

Heparin, one of the complex carbohydrates known as mucopolysaccharides or glycosaminoglycan, is currently used to prevent formation of clots. In general, heparin is well tolerated and devoid of serious consequences. However, it allows platelet adhesion to foreign surfaces and may cause hemorrhagic complications such as subdural hematoma, retroperitoneal hematoma, gastrointestinal bleeding, hemorrhage into joints, ocular and retinal bleeding, and bleeding at surgical sites. These difficulties give rise to an interest in developing new methods of hemocompatible materials.

Many different groups have studied immobilization of heparin on the polymeric surfaces, heparin analogs and heparin–prostaglandin or heparin–fibrinolytic enzyme conjugates. The major drawback of these surfaces is that they are not stable in the blood environment. It has not been firmly established that a slow leakage of heparin is needed for it to be effective as an immobilized antithrombogenic agent; if not, its effectiveness could be hindered by being “coated over” with an adsorbed layer of more common proteins such as albumin and fibrinogen. Fibrinolytic enzymes, urokinase, and various prostaglandins have also been immobilized by themselves in order to take advantage of their unique fibrin dissolution or antiplatelet aggregation actions.

-Albumin-coated surfaces have been studied because surfaces that resisted platelet adhesion ***in vitro*** were noted to adsorb albumin preferentially .

-Fibronectin coatings have been used in ***in vitro***endothelial cell seeding to prepare a surface similar to the natural blood vessel lumen.

-algin-coated surfaces have been studied due to their good biocompatibility and biodegradability.

- plasma gas discharge and corona treatment with reactive groups introduced on the polymeric surfaces have emerged as other ways to modify biomaterial surfaces.

-Hydrophobic coatings composed of silicon- and fluorine-containing polymeric materials as well as polyurethanes have been studied because of the relatively good clinical performances of Silastic, Teflon, and polyurethane polymers in cardiovascular implants and devices. Polymeric fluorocarbon coatings deposited from a tetrafluoroethylene gas discharge have been found to greatly enhance resistance to both acute thrombotic occlusion and embolization in small diameter Dacron grafts.

-Hydrophilic coatings have also been popular because of their low interfacial tension in biological environments.

-Hydrogels as well as various combinations of hydrophilic and hydrophobic monomers have been studied on the premise that there will be an optimum polar-dispersion force ratio which could be matched on the surfaces of the most passivating proteins. The passive surface may induce less clot formation.

-Polyethylene oxide coated surfaces have been found to resist protein adsorption and cell adhesion and have therefore been proposed as potential “blood compatible” coatings.

General physical and chemical methods to modify the surfaces of polymeric biomaterials are listed in Table 2.

**TABLE 2** Physical and Chemical Surface Modification Methods for Polymeric Biomaterials.

|  |  |
| --- | --- |
| To modify blood compatibility | Silicon containing block copolymer additive  Plasma fluoropolymer deposition  Plasma siloxane polymer deposition  Radiation-grafted hydrogels  Chemically modified polystyrene for heparin-like activity |
| To influence cell adhesion and growth | Oxidized polystyrene surface  Ammonia plasma-treated surface  Plasma-deposited acetone or methanol film  Plasma fluoropolymer deposition |
| To control protein adsorption | Surface with immobilized polyethyelenglycol  Affinity chromatography particulates  Surface cross-linked contact lens |
| To improve lubricity | Plasma treatment  Radiation-grafted hydrogels  Interpenetrating polymeric networks |
| To improve wear resistance and  corrosion resistance | Ion implantation  Diamond deposition  Anodization |
| To alter transport properties | Plasma deposition (methane, fluoropolymer, siloxane) |
| To modify electrical characteristics | Plasma deposition  Solvent coatings |

Another way of making antithrombogenic surfaces is the saline perfusion method, which is designed to prevent direct contacts between blood and the surface of biomaterials by means of perfusing saline solution through the porous wall which is in contact with blood. It has been demonstrated that the adhesion of the blood cells could be prevented by the saline perfusion through PE, alumina, sulfonated/nonsulfonated PS/SBR, ePTFE (expanded polytetrafluoroethylene), and polysulfone porous tubes.