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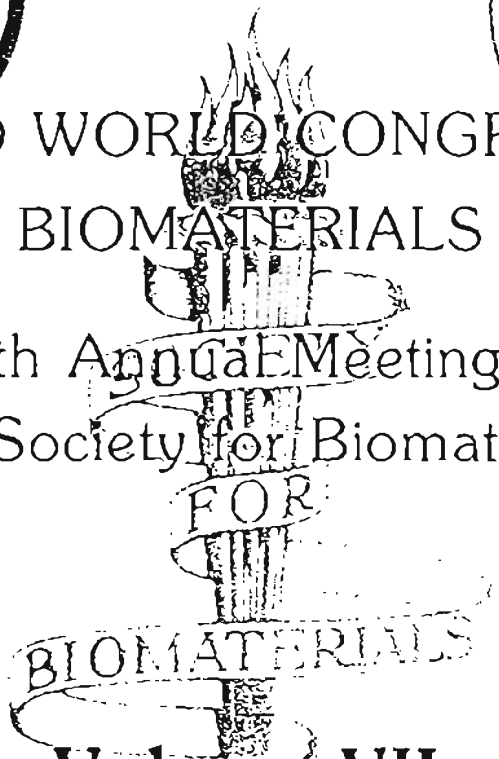

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THE ROLE OF POLYMER PROPERTIES AND FABRICATION PROCESS IN DETERMINING THE BLOOD COMPATIBILITY OF NEW THERMOPLASTIC ELASTOMERS

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Hemocompatibility is not a characteristic depending only on chemical properties of materials. In the last few years it has been observed that materials potentially hemocompatible with regards to their chemical structure, proved to be unsatisfactory for the fabrication of prostheses in contact with blood.

Quite recently some Authors (1) have pointed out the important role, for the blood compatibility of a prostheses, both of the physico-mechanical properties of material and of the fabrication processes which can vary the porosity and the surface characteristics.

In the attempt to improve the final hemocompatibility (i.e. that showed by prostheses in vivo) of new polymers, synthesized in our laboratories and already showing good hemocompatibility (from in vitro tests) based on their chemical structure, we are now studying different fabrication processes which can modify the bulk and surface properties, when used for the production of cardiovascular prostheses.

The new thermoplastic elastomers (TPE) already synthesized in our laboratories belong to the following two different categories (2):

1. new comb-like TPE obtained by reacting styrene-isoprene (pSt-b-pI) or styrene-butadiene (pSt-b-pBu), two block polymeric chains, with either ethylene-maleic anhydride (EMAC) or styrene-maleic anhydride (STYMAC) copolymers (Fig. 1). These new copolymers present a very high degree of hemocompatibility due to the presence of $-COO^-$ groups;
2. new polyurethanes prepared by reacting , diols with different diisocyanated followed by the reaction with various chain extenders. As an example, by the use of α, ω polyisobutylene diols with MDI and 1,4

cycloexanedimethanol or ethilenediamine as chain extenders, the following two polyurethanes are obtained (Fig. 2).

All these polyurethanes have shown blood compatibility from in vitro tests similar to that shown by other biomedical polyurethanes.

The mechanical properties of the new TPE's have been varied over a wide range by modifying the ratio of hard and soft segments.

These materials have been used for the production of both valvular and vascular prostheses.

A new type of prosthetic leaflet heart valve has been manufactured using composite materials (3). The three leaflets of this valve consist of a layer of knitted Dacron or Kevlar fabric, to ensure mechanical resistance, coated with TPE, using different techniques, to increase the hemocompatibility.

Small diameter ($\leq$ 5mm) vascular grafts have been fabricated using TPE with different properties and using various fabrication techniques, in order to impart to the grafts both a compliance very similar to that of natural vessels and a porosity which allow the tissue ingrowth and the new intima formation (4). The fabrication processes investigated are:

1. coating an appropriate mold with a solution of the polymer and evaporating the solvent;
2. coating with a polymer solution, then immersing the mold in water and drying it in a heated forced-draft oven;
3. process as in 1 or 2 but with imbeded helical wound Dacron fiber in order to obtain a not kinking graft;
4. extrusion processes with phase inversion of polymer solution in a water bath;
5. sprying of polymer or polymer blend solution.

By the use of these techniques, grafts which show different hemocompatibility, in "vivo" experiments, have been obtained.