Introduction

A major goal of this symposium was to examine the present system for the manufacture and testing of standard grafts in current clinical use. The emphasis focused on the up-to-date technical advances that will influence or are now influencing the design, safe and effective use, and management of vascular graft prostheses.

It is hoped that this conference was the initial step in stimulating a greater interest in the evaluation and safety of current graft prostheses, and will lead to rational standards for vascular materials. The impetus has come from the Food and Drug Administration (FDA), whose interest lies in the development of standards for vascular grafts. The variety of implantable products available on the market and the different materials manufactured in several configurations has led to specialized classes of graft products and techniques, each with their own specific merits and disadvantages.

Considering the growing use of these prostheses as effective and permanent arterial substitutes, the issues addressed at this meeting included biocompatibility as well as durability test methods, and the establishment of minimum safety and effectiveness requirements for each type of graft. Two types of events were included within the conference program. The technical plenary sessions were short, intensive preparations of current work and results by experts in the field. A workshop session was organized for in-depth oriented discussions of the problems, directions, and immediate goals in the area of vascular graft development.

The Workshop and complete discussion sections are found at the end of the text and a Summary of all papers is also presented.

This STP contains papers written by leaders in their fields who provided a comprehensive overview in four major areas:

1. the clinical overview of current prosthetic grafts and requirements as perceived by the surgeon;
2. a review of the material properties and performance criteria of commercially available vascular prosthesis on the market;
3. the methods for retrieval and analysis for evaluation and prediction of long-term graft function for grafts implanted in both experimental animal models and in man; and
4. the analysis of biocompatibility and biodegradability issues relevant to manufacturing technologies, packaging, sterilization, and so forth.
The clinical success with diverse prosthesis and prosthetic materials have been remarkable but offset by serious complications and graft failures. Nevertheless, improved materials, design, and evaluation procedures are needed and more clearly identified and defined.

The sponsors include ASTM, known worldwide for its effective standard setting techniques, the FDA, the regulatory arm of the government, and the International Center for Artificial Organs and Transplantation (ICAO).

The International Center for Artificial Organs and Transplantation operates and maintains an information education center and museum for the education of the professional lay public in the historical development, current state of the art, and future development of artificial organs and organ transplantation. Located in Cleveland, Ohio, the ICAOT is operated under the trusteeship of the International Society for Artificial Organs.

We are grateful to these three organizations for arranging this symposium. We are especially grateful to the distinguished speakers who shared with us their research and work and to the chairmen of the sessions who included Dr. James Stanley, Mr. Robert Whalen, Dr. Stanley Brown, Dr. James Anderson, and Dr. Yukihiko Nosé.

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