

Overview

This volume provides papers presented in November 1985 at a symposium on the characterization and performance of porous biomaterials used for surgical reconstructions of musculoskeletal systems.

The symposium was organized to bring together contributors from private practice, government and industrial research laboratories, universities, and other fields with related interests, in an attempt to describe what has been done in this field, what we are doing now, and what our plans are for the future. This book reflects the state-of-the-art-and-science information on porous biomaterials publicly available during late 1985. Clearly, all basic and applied research and development activities are not included; however, the omissions were not intentional. The efforts of the symposium session chairmen, S. Brown, E. Frisch, and J. Parr, contributed significantly to the initiation, organization, and finalization of the program activities. These efforts are applauded.

Applications of porous biomaterials for the fixation of surgical implant prostheses through tissue ingrowth have expanded significantly during the 1980s. A great need for expanded information exchange and standardization of evaluation methods continues to exist, in part because of the number of materials, manufacturing techniques, designs, surface modifications, variations in porosity dimensions, and device applications.

This volume, like the symposium, is separated into topic areas to combine interrelated investigations. These topics include the mechanical properties of porous coatings, mechanical properties of substrate and coating, characterization of pore dimensions, biodegradation and biological analyses, performance in humans and laboratory animals, modeling and implant fixation, and systems for future applications.

The various standards and recommended practices of ASTM Committee F-4 on Medical and Surgical Materials and Devices can be separated into those on materials, those on test methods, and those on performance. Within the materials area, most ASTM standards provide details on the chemical analyses, basic properties, and surface finishes. A significant need exists for similar standards for porous biomaterials and devices. One result of the symposium was the development of several task force activities to address key needs related to the applications of devices utilizing porous biomaterials. A number of recommendations and task force activities evolved during the symposium discussions.

An overview of the findings in these papers, summarized by topic area, follows:

Mechanical Properties of Coatings and Substrates

The papers in the first two sections, which are on basic material characteristics, coatings, and coating-substrate properties, provide detailed reviews on mechanical performance measurements as a function of manufacturing, specimen and test design, and materials. Interestingly enough, and critically, the relative strengths of the porous-surfaced alloys were between 0.25 and 0.8 of the alloys' ultimate tensile strengths. Tension, shear, and fatigue test data showed a very strong dependence on the test and specimen designs. This phenomenon, combined with the authors' strong recommendations on the need for standardized quality analysis and assurance test methods for porous coatings, emphasizes the need for considerable additional research and development in this area. The necessity of careful

design and application to minimize fatigue fracture is stated by many of the authors. This, certainly, is a critical concern of all involved. An ASTM task force continues work in this area.

One aspect of the materials characterization focuses on alloy chemical analysis for porous and nonporous conditions, gradients, and localized regions of impurity concentrations and on how these might influence mechanical and biological performance. Although limited data exist, strong recommendations for additional studies are made with regard to both cobalt-based and titanium-based alloy systems.

Characterization of Pore Dimensions

Most analyses of properties depend on structural characterizations to establish structure versus property relationships as a function of the manufacturing process. The papers in this section provide basic guidelines on methods to characterize the pore size, distribution, and connectiveness. Systems and techniques for hand and automated quantitative microscopy provide various measurements of the pore mean intercept, volume fraction, surface area in the volume, areal fraction, genus, and other parameters. The importance of these measurements as a function of the material and device application is emphasized. Clearly, true three-dimensional characterizations will be required in order to interpret all types of *in vitro* and *in vivo* information. An ASTM task force continues work in this area.

Biodegradation and Biological Analyses/Performance in Humans and Laboratory Animals

Laboratory, laboratory animal, and human investigation results are presented in an attempt to correlate corrosion, biodegradation, measurements of elemental distributions within laboratory animals, and excretions from humans currently implanted with porous biomaterial prostheses. The biological significance of metallic ions is also reviewed from laboratory animal results.

During the symposium, a number of concerns were expressed after the laboratory and laboratory-animal-related presentations with regard to local and systemic tissue responses. However, the early human data have produced mixed opinions and a position that no clear-cut correlations exist between the human and laboratory results. There continues to be a very significant need for additional clinical and laboratory data in this area. At this time, it is not possible to define dose-response-time relationships clearly for elements released from existing porous implant systems. Since this is a multifactorial area of research, additional studies are strongly recommended.

Modeling and Implant Fixation

One objective of the research community has been better definition of the implant characteristics associated with force transfer through mechanical and biomechanical properties, while independently considering the transfer of elemental species through chemical and biochemical property evaluations. The laboratory animal and human studies completed within the past three to five years have shown important correlations between ingrowth characteristics. However, the need for standardized evaluation criteria is supported for both porous and nonporous devices. Laboratory and laboratory animal modeling studies provide key insights into device limitations; however, considerable discussion was associated with the extrapolation of existing data. Although no ASTM activities were suggested at the symposium, additional basic research is strongly recommended.

Systems for Future Applications

A number of metallic, ceramic, and polymeric materials in the form of porous implant devices are reported on in the last section of this volume. Lengthy discussions at the symposium presentation followed several of the papers with regard to the interpretation of the information provided. These reactions showed clearly that the research and development activities related to porous biomaterials and their applications remain a dynamic field of worldwide interest.

Future research, development, and applications of prostheses that are fixed through tissue growth into porosities certainly provide an area for continued activity. All of the contributing organizations and authors are to be complimented for bringing this information to presentation and publication. The volume should provide worthwhile references. The editor strongly recommends the continued and expanded involvement of the industrial sector in this type of public disclosure and information transfer.

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