Overview

Biomaterials perform diverse biological functions. Understanding the process controlling the mechanical properties is important for materials in medical device use. The mechanical properties of coatings and composites depend on their deformation and fracture mechanisms. When stresses are applied that exceed the yield strength, plastic deformation can occur resulting in mechanical damage. As a majority of structural metallic materials reside in aqueous environments, the corrosion and degradation of metallic systems can result in device failure oftentimes coupled with the migration of particulate debris. The impact of device failure on the well-being of an implant recipient can be traumatic. Such findings have demanded more stringent acceptance criteria for mechanical and chemical properties of both surface and bulk materials.

In planning this book, the editors chose to attract contributors not only from the cardiovascular areas, but to include scientific and clinical interests and common goals in the areas of urological, orthopedic, and polymeric research. The choice of test methods, experimental design data analyses, and selection of test models presented a range from cellular to implant devices. In order to define the proper test configurations, judgments were made as to which test criteria and test methods were identified. The criteria and the application of engineering principles would become clear and comprehensible to potential regulators and users in the medical community.

Therefore, this Special Technical Publication was compiled as a review of the 1992 Symposium on Biomaterials' Mechanical Properties held in Pittsburgh, Pennsylvania.

The Table of Contents is composed of a collection of 24 papers which have been grouped into 6 major categories. These include: (1) methodologies for testing cardiovascular materials, (2) adhesives, films, and plastics, (3) the evaluation of metallic materials and bone, (4) composite materials, (5) urologic materials, and (6) future directions.

Cardiovascular Materials

One fundamental assumption underlying the mechanical approach to the analysis of cardiovascular materials is that they undergo cyclic deformation and require a blood-compatible surface. Hayashi begins with a look at fatigue properties that are crucial to the endurance, reliability, and safety of implants. Using the segmented polyether urethanes as a model, he has outlined the evaluation of materials by application of different test environments, temperature, and cyclic rate on the tensile and fatigue properties. Computer data acquisition and processing have established a relevant database for comparison with future accelerated endurance test methods.

Two papers in this group have focused on the durability of materials in heart valves. Lee et al. have combined structural analyses (biochemical and histological) with mechanical testing for the examination of the viscoelastic behavior of collagenous bioprosthetic tissues. Implementing a high strain rate uniaxial test apparatus, large deformation cyclic loading and small deformation forced vibration studies at frequencies of up to 10 Hz were applied. Stress relation studies with loading times of 0.1 s or less are used to characterize various treatments of collagenous tissues used for heart valves. They have correlated changes in extensibility and stress relaxation behavior with mechanical properties. Based on these results, they suggest a high strain rate by biaxial testing for future studies.

Teoh et al. have designed a test rig to simulate the impact-sliding action mechanism of wear between the struts and disc occluder of a mechanical heart valve. Performed at body temperatures and 3 Hz, the design accelerates wear. The areas of contact are held constant and wear profiles are monitored using a surface profilometer and visualized by SEM. This method has the advantage of early wear detection.

Microstructural defects introduced into vascular grafts made from expanded PTFE by the use of running sutures or forcep compression reduce the internodal distance adjacent to the anastomosis. Holubec et al. have reported that impaired healing results when the internodal distance is reduced to 10 μm or less. Analysis of the optimum PTFE ultrastructure and cellular ingrowth on healing was evaluated in dog and rat models. Such studies are pertinent to the development of a small vascular prosthesis of 4 mm or less in internal diameter.

Yokobori et al. evaluated the effects of encapsulation of the vascular substitute and of sutures on the anastomotic strength. Using a pulsatile pressure flow test system, the *in vitro* tensile anastomotic strength and the *in vitro* pulsatile flow through pressure tests (Δ p 110–294 mmHg) were performed on polyester vascular grafts. Identical suture techniques were used, and grafts were implanted in dogs and tested after three months. Although the *in vitro* tests confirmed the strength of the vascular graft, *in vivo* tests were necessary to describe the enhanced effect on strength due to tissue adhesion and encapsulation.

Adhesive Films and Plastics

A prediction of material failure and the optimal stresses used in the design of components to prevent premature failure are concerns expressed by Teoh in his paper concerning the design stresses of medical plastics. The modeling of the creep rupture behavior of plastics has identified upper stress values prior to fracture and lower stress limits maintained without failure. Based on these data, Delrin® was given as an example with stress limits corresponding to its applicability in mechanical heart valves but not in joint prostheses.

The formation of bonded interfaces may produce microscopic flaws which could promote interfacial failures. Moon et al. investigated the mechanical properties of tooth adhesive resins to determine if bond strengths approach the cohesive strength of the materials and for finite element evaluation of polymerization shrinkage bond stress. Data were obtained for the elastic moduli, breaking strength, and deformation. They conclude that strength values could limit the bond strength.

Peterson presented a technical report on problems correlating porous coating pull-off strength results with the use of test coupons. The use of Taguchi methods was described to isolate the variables causing test result differences.

Evaluation of Metallic Materials

Joint prostheses must fulfill demands regarding tissue compatibility and particular mechanical properties. Bone tissue is a dynamic material having the potential to adapt to its environment. Bone research has contributed greatly to our understanding of bone mechanics. The papers in this section address the challenges in joint replacement, namely, adverse bone remodeling and the generation of particulate debris that arise from metal/bone fretting or abrasion.

Bhambri and Gilbertson have evaluated the fretting fatigue behavior of head/taper combinations used for total hip replacements. Fatigue tests were performed with simulated body fluids within a cell designed to retain particles greater than 0.25 μm. SEM and EDAX were used to characterize the particles. The advantages of a surface nitriding treatment were discussed to reduce fretting.

In order to study the viscoelastic properties of bone, Tanabe et al. assumed that the behavior of bone could be represented by a three-element standard linear model. Experimental data obtained by analysis of the split-Hopkinson pressure bar (SHPB) tests were confirmed by results from experiments and ultrasonic measurements done on bovine femoral bone. These methods may reduce the time required to characterize mechanical properties of bone.

The strength of regenerate bone was evaluated by Miyasaka et al. Experimental callotasis was developed in a rabbit femoral model. The developed callus showed hysteresis in uniaxial tests and stress relaxation. The technique of external fixation, the rate of destruction, and the quality of the callus are important parameters in the use of the callotasis method and in the evaluation of the viscoelastic model for the developing elongated callus.

Higo and Tomita described a fatigue test employing a four-point side notch bend specimen for evaluating the components of artificial joints. Corrosion was measured by comparing fatigue in an air environment to that of physiological saline. Galvanic pico-corrosion tests and crevice corrosion were examined.

Flemming et al. identified a fretting component at the cone-taper interface of modular total hips that may be a factor in the corrosion observed in this area. Interface fretting was studied by measuring current during the cyclical loading of hips in a universal testing machine. The taper fretting current was measured and compared for two different hip designs. The current mechanical test method was the most appropriate method to study corrosion of the hip cone and taper. This method was applied to study the variability of neck extensions and its contribution to the resulting corrosion. This paper was chosen as the first winner in the newly inaugurated Student Paper Competition sponsored by the ASTM Committee F-4 on Medical and Surgical Devices and Materials. The competition is open to all students of members of the ASTM Committee F-4. This award includes a $500 stipend and award certificate. Mr. Flemming is a graduate student of Dr. S. Brown, Department of Biomedical Engineering, Case Western Reserve University, Cleveland, OH.

Nakamura et al. introduced the importance of using *in vitro* cytotoxic studies in the evaluation of materials in the oral environment. Dental amalgams were subject to dynamic extraction with suspended, freely moving, and static specimens using various media and temperature conditions. Extracts from all materials were evaluated by cell culture and atomic absorption spectroscopy. The *in vitro* method is suggested as a candidate simulation test that may be effective in evaluating the adhesive strength of cells on biomaterials.

Ligaments support the joints, and injury to the anterior cruciate ligament (ACL), for example, destabilizes the knee, often leading to osteoarthritis. Stewart et al. examined ligament implant fixation devices. A quantification of loads placed on these tissues relative to normal tissue function and the method of device fixation are topics related to rehabilitation and healing.

Composite Materials

The use of soft or hard tissue composite materials imposes specific mechanical and biocompatibility demands. They permit a greater manipulation of their stiffness to accommodate implant design. Latour and Black have outlined a collaborative effort for determining the bond strength and environmental resistance between fiber-reinforced polymer composite materials for medical applications. Test fiber microdroplet samples under both static and dynamic loading and conditions for diffusional equilibrium reduce the time required for testing. This method should be useful for the development of composite biomaterials resistant to *in vivo* mechanical degradation.

The accelerated degradation of polymer composites was also reported by Jockisch et al. Carbon fiber reinforced PEEK injection molded bendbars, cut in four sections of the bendbar, were used to evaluate local microstructural variations in composites. Fracture surfaces and flexure testing of the miniflexbars were sensitive to local variations in microstructure. Small-scale specimens may be valuable in the analysis of mechanical properties of composites.

Gilbert and Dong have introduced a novel method that uses stress relaxation experiments whereby strain is applied to a sample, and the stress decay response is measured over time with analog-to-digital data acquisition. Laplace transformation techniques are employed. A three-dimensional relationship between complex modulus, frequency, and temperature can be constructed. The changes in stiffness of a material can be monitored under a variety of experimental conditions.

The problem of calcium salt deposits and the failure of biomedical polyurethanes was addressed by Wong and Benson. The fracture behavior of Biomer® and Pellethane® indicate that with a high concentration of salt, the salt disrupts the intermolecular faces leading to structural changes manifested in the strain energy to failure.

Leadbetter et al. introduce the use of absorbable microcomposites and fiber-reinforced composites with hybridized interfaces. The strength of interfacial bonding is crucial for these composites. Absorbable materials may offer the advantage of eliminating second surgeries and may replace metallic components with their apparent corrosive problems.

Urologic Materials

The three papers in this section on the biomechanics of the ureters and urinary calculi seem to be a point of departure for the entire book because the topic deals with *in vivo* tissue testing. The papers of Uchida et al. and Watanabe et al. in this section deal with the problem of the generation of urinary calculi in the kidney and ureter. Conventional therapy suggests open surgery, but attempts for extracting the calculi require data on the calculi themselves and on the properties of the ureter.

Uchida et al. identified a program for the intracorporeal destruction of urinary calculi with a technique they called "microexplosion lithotripsy." The chemical analysis and compressive tensile strengths of calculi were determined under wet and dry conditions. Based on these data, a transmitted shock wave exceeding the compressive strength of the calculus causes the destruction of urinary calculi and release of gas bubbles. These techniques may be applicable for the removal of calculi measuring 7 mm in diameter and below.

Tension and pressure testing of cadaver ureters was performed by Watanabe et al. to examine the transverse and longitudinal properties of the ureter and maximum increase in diameter prior to leaking. Samples from the longitudinal direction were four times stronger than those in the transverse direction. Damage to the ureter may go undetected under certain conditions.

The third paper in this group from Saitoh et al. analyzed the *in vivo* mechanical properties of the canine, the normal bladder, the denervated bladder, and denervated bladder two weeks after denervation. Mechanical data were obtained using suture markers placed on the bladder. A computer analysis based on Glantz's mathematical model for smooth muscle was used to evaluate changes in the stress strain curves. The mechanical properties of the bladder are essentially viscoelastic.

Future Directions

The last section of this book poses a question as to how the biomaterials community will address the issues of quality, safety, and efficacy in the experimental testing of materials. This area of increasing interest to clinicians, device manufacturers, and basic scientists. The aforementioned papers in this STP attest to illustrate the challenges and complexities of biomaterials testing. The listing here is far from complete. While the transition from experimental research to clinical or market acceptance depends on good design, adequate testing, and quality control assurance, of utmost importance are good manufacturing and laboratory procedures. Unless we outline these priorities, how and what we test may be meaningless. This section also highlights research opportunities in areas involving biomaterials-based technologies, tissue engineering, and cutting-edge methodologies.

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