

Summary

The papers in this book are grouped together in sections based on the topics covered. The first group deals with *in vitro* studies of metallic materials and is concerned with corrosion processes and behavior, hydrogen embrittlement, and stress corrosion cracking. The second section that covers metallic materials *in vivo* and *in vitro* deals with corrosion-fatigue, fretting polarization behavior, and electro-polishing. Aneurysm clip materials, fatigue of ball-joint rods, electro-chemical studies of dental alloys, and arc plasma sprayed coatings are topics covered in the third section. The fourth section covered biological effects of metallic implants and the fifth section deals with biocompatibility and durability of polymeric materials including silicones and polyesters. The sixth session deals with degradation of polyurethane, adsorbable, and biodegradable materials. Wear of polyethylene, tricalcium phosphate ceramic and loosening of cemented hip stems are considered in the seventh session. The final section addresses retrieval, performance standards and pluralistic risk management, regulation, and litigation. The individual papers in each section are summarized here in general terms but the papers should be read for specific information.

Basic corrosion processes for implant alloys are discussed by N. D. Greene who relates corrosion of metals in the body as being similar to corrosion of metals in aerated sodium chloride. Emphasis is placed on the appropriate selection of metals for implants. Equations for oxidation and reduction are given, and it is explained that due to the low rate of corrosion of implant metals, the best technique for measuring the rate of corrosion of implant metals is by the linear polarization method. Corrosion of implants can accelerate mechanical failure or fatigue. Hydrogen embrittlement or stress corrosion or both have not been a problem with the cobalt-chromium-molybdenum alloy, but Edwards et al found that the hydrogen that is generated at the surface when the cobalt-chromium-molybdenum is cathodic can be adsorbed and embrittle the material. Some experiments charged the specimen with hydrogen. These studies point up that if hydrogen were available, a loss of ductility could arise. The hydrogen build-up in this material could occur over time if a crack tip and suitable conditions existed. Hydrogen embrittlement, in general, is not a problem with the cobalt-chromium-molybdenum implant alloys but improper design or creviced areas could accentuate this potential problem.

Kumar et al investigated properties of cast, wrought, and powder metallurgy (P/M) processed cobalt-chromium-molybdenum alloys. The large-grained cast material had lower tensile strength and ductility than did the wrought or P/M processed small-grained materials. Wrought materials had small equiaxed grains

with some twinning and with fine-grain boundary carbides. Carbides in the P/M material were fine and dispersed throughout the grain and grain boundaries. The P/M materials made from coarser powders (60/100 mesh as opposed to 250 mesh) had larger carbides and reduced mechanical strength over the other P/M material and wrought materials but greater than the cast material. All materials showed identical corrosion behavior and high corrosion resistance to Ringer's solution, but pitting tests in 0.01 M HCl resulted in the 250 mesh P/M material being the most resistant to the four types and the 60/100 mesh P/M material being the least resistant. All materials showed pitting in the HCl, but all were more resistant than Type 316L stainless steel. The fine-grained materials of the wrought and P/M types were more susceptible to stress corrosion cracking than the cast material in boiling 30% MgCl₂. No susceptibility to stress corrosion cracking was found in tests with Ringer's solution.

Sheehan, Moran, and Packer studied stress corrosion cracking (scc) of Type 316L stainless steel *in vitro*. Tests in this investigation were conducted using Type 316L specimens with electropolished surfaces for slow strain rate tension tests and Schneider intramedullary nails in the static bend tests. They concluded, as previous investigators had done, that scc is not a mode of failure of Type 316L stainless steel implants *in vitro* and found no indication that scc of this material would occur *in vivo*. Bundy and Desai studied scc of Type 316L stainless steel and ELI Ti-6Al-4V using fracture mechanics specimens and measuring crack propagation velocity versus stress intensity in environments of MgCl₂, HCl, and Ringer's solution. Crack propagation occurred in precracked Type 316L stainless steel in Ringer's solution held at a potential that disrupted the passive film. The conclusion from this investigation was that scc of Type 316L stainless steel could occur *in vivo* if these conditions existed.

Piehl et al reported on corrosion fatigue of hip nails and emphasized the importance of materials selection and design. Corrosion-fatigue tests of nail plates were conducted on a flexure fatigue machine to compare devices of identical design but different material. Large plate designs had superior corrosion-fatigue performance over small plates. Devices made of Ti-6Al-4V were superior in corrosion-fatigue performance to the Type 316L devices even though some fretting and wear occurred in the countersinks.

Brown and Merritt reported on *in vitro* fretting corrosion testing of bone plates and screws, and effects of blood serum and other proteins were investigated. Oscillatory motion experiments at a frequency of 1 Hz were run for 14 days and were followed with weight loss measurements. Results showed that protein additions significantly reduced fretting corrosion of stainless steel and the cobalt-nickel-chromium alloy, had no effect on Ti-6Al-4V, and increased fretting corrosion of pure titanium. These effects did not change the corrosion resistance ranking of the materials, and it was concluded that protein additions and associated precautions were not necessary for ranking alloys with this test involving fretting corrosion.

Ogundele and White carried out polarization measurements in Hanks' physiological solution on two stainless steels, Type 316L and SG2SA, both meeting ASTM Specification for Stainless Steel Sheet and Strip for Surgical Implants (F 56-78) composition specifications. The Type 316L stainless steel had a breakdown potential of 200 mV versus saturated calomel electrode (sce), while the SG2SA stainless steel had a breakdown potential of 300 mV versus sce. The difference was attributed partially to microstructural differences and to small variations in molybdenum and other elemental composition in the latter alloy. The corrosion potential for both materials shifts to a more negative value with the addition of Cl^- ions and to a more positive potential with the addition of HCO_3^- ions. These stainless steels can undergo active corrosion in highly acidic solutions below -300mV versus sce but are not corrosively active in physiological saline solutions below the breakdown potential.

Stainless steel implants may be electropolished as one of the final surface preparation steps. The paper by Irving describes the basic electrochemical principles of electropolishing as well as the commercial process for electropolishing. The increased corrosion resistance of electropolished Type 316L stainless steels is noted and several factors are given to account for this improvement including removal of a deformed surface layer, surface roughness, and other surface variations. Caution should be exercised when using electropolishing solutions and procedures. Further studies of electrolytic solutions, surface films, and other variables are needed to maximize benefits of the electropolishing process.

Aneurysm clips, used to isolate a potentially fatal vascular aneurysm, are currently made from a variety of metallic alloys. Kossowsky, Kossovsky, and Dujovny examined commercially available clips made from 17-7ph, Type 304, both U.S. and British Type 316 stainless steels, and MP35N using a variety of metallurgical techniques including corrosion resistance measurements. Additionally, they performed failure analysis on one device made of 17-7ph which had been retrieved after failure *in vivo*. Their work suggested that some of the alloys used are too susceptible to stress corrosion to be recommended for permanent implantation. Indeed, this was believed to be the mode of failure of the retrieved clip. They suggest that clips that show a lower corrosion resistance than Type 316 stainless steel should not be used for permanent implantation.

Donald, Seligson, and Brown considered the fatigue of ball-joint rods used in external fixation devices. It is interesting that while much work has been done on fixation devices that are never used more than once, such as bone plates, very little study has been directed at the problem of fatigue in external fixation devices that may be reused. The authors concentrated on the ball-joint connectors in doing fatigue tests that indicate that the endurance limit of these connectors is below 400 N. Since some configurations in which these devices can be used result in loads higher than this value, the authors suggest that guidelines be evolved governing the reuse of such devices.

A new electrochemical technique to determine the susceptibility of dental

alloys to sulfide tarnishing was developed by Marek. This technique requires careful control of experimental parameters such as temperature, sulfide solution composition, and potential. Using coulometric techniques, an index of susceptibility to tarnishing can be established. This elegant test offers an opportunity to achieve objective, quantifiable results that previously were not possible.

With increasing use in orthopedic implants, it is important to have established methods of determining the mechanical properties of the porous metals used in many devices. Hahn et al reported the results of mechanical testing of titanium coatings manufactured using the plasma spray technique. Both the result of their testing and their method of testing is of interest. Their results showed shear strengths in the 5.6 to 9.9 MPa range and tensile strengths in the 5.1 to 25 MPa range. Corrosion fatigue tests indicated no effect on endurance limit of the substrate provided that no sintering was performed. Sintering of the samples above or below the beta transus resulted in lower endurance limits.

A very interesting session on *in vivo* effects of corrosion products included papers by some of the foremost researchers in the area. Merritt and Brown have done extensive work on the biological effects of corrosion products. The paper presented here focuses on the *in vivo* responses to corrosion products of stainless steel and cobalt-chrome alloy devices. The work included study of the sensitivity responses using the LIF test, infection studies in animals, protein binding of metal salts and the distribution of metal salts in the body. The results suggest that patients sensitive to the metallic constituents of stainless steel or cobalt-chrome may be unable to defend adequately against infection due to a loss of spontaneous white blood cell migration. This question remains unanswered. However, it would appear from the animal testing that the ability to fight infection may be enhanced in the short term but reduced chronically.

Lucas, Bearden, and Lemons examined the ultrastructure of cells from rabbits and human gingiva that had been exposed to Type 316L stainless steel solutions. The cellular response to the solutions was correlated with the *in vivo* condition. The severity of the cellular response increased with increasing concentration of the stainless steel solution. This microscopic evaluation technique may be helpful in interpreting the results of macroscopic histological examinations.

Smith and Black used a novel method of estimating the corrosion rate of Type 316L stainless steel by examining the systemic transport and distribution of corrosion products in laboratory rabbits. They showed a positive correlation between implant surface area and the levels of iron and chrome circulating in the blood and accumulated in the liver. They approximated the corrosion rate of the implant by evaluating these levels and found the rate to be consistent with the reported corrosion rate of Type 316L.

Marchant et al use a cage implant system to study the biocompatibility of materials by focusing on the acute inflammatory response and the associated reactions. The cage is made of wire mesh Type 316 stainless steel, and the polymer or implant of interest is placed within this cage. Prior to tissue growth,

the cage is filled with exudate resulting from the presence of the foreign materials. This exudate can be aspirated from the site using a sterile needle and syringe and then studied in terms of cell types, activities, etc., to characterize some of the complex reactions of the inflammatory response. Studies of the inflammatory response in rats were reported for the cage only, a biodegradable hydrogel, poly(2-hydroxyethyl-L-glutamine)(PHEG), and with added injections of a chemotactic tripeptide solution to increase the acute phase reaction. An acute inflammatory reaction with increased white cell concentration occurred in all cases, but the exudate from the PHEG implant system indicated increased cell formation and activity. Details of the inflammatory response of this study are discussed, and these results show that the cage system can be used as a model for studying the body's reaction to implant materials.

Swanson et al reported on biocompatibility of silicone implants in animals and humans ranging up to 12 years of implantation. Using pathological and radiological techniques, they assessed host reaction to various implants. Their results showed smooth fibrous encapsulation of the implants in dogs with no bone resorption or bursa formation. Although wear particles from the implants were evident in both the animal and human studies, the particles appeared to be well tolerated with minimal inflammatory cells and no necrosis. A single enlarged lymph node in the human showed a mild benign foreign body reaction. No evidence of particle transport was evident from pathological examination of organs in either human or animal cases.

Silicone elastomers have been used successfully in implant reconstructive surgery since the middle of the 1950's, and the finger joint prosthesis is one implant with which this material has made a great improvement. This background is provided by Frisch and Langly along with information regarding chemistry, fabrication, and biocompatibility of silicone elastomers. Their paper reports on the biodurability and high performance of a new silicone elastomer. Tests, utilizing ASTM procedures, showed the new high performance material to have a low modulus, high tear propagation strength, and high resistance to flexural fatigue crack growth. *In vivo* studies of the material in dogs over a two-year period showed no change in the physical properties. There is a 2% by weight of polydimethylsiloxane that is not chemically bound in the elastomer. Based on test data of extractions before and after implantation, the authors concluded that no significant loss of silicone to tissues occurred. Lipid absorption occurred early after implantation and was 1.5% at the end of 104 weeks, but this did not appear to affect the properties of the material.

King et al present the results of a study of the biodegradation of vascular prostheses made of poly (ethylene terephthalate), PET. Physical and chemical factors are given as contributing factors in the loss of mechanical performance and bursting strength of this material. Retrieved implants of PET material were obtained after having been implanted for periods of a few hours to 14 years. Unused control specimens of all samples, except in two cases, were used for

comparative tests of bursting strength, stitch density, molecular weight, and carboxyl group content. There was a loss in bursting strength, a loss in molecular weight and an increase in carboxyl group content for the implanted PET material. It was estimated that 25% of the initial bursting strength was lost after 162 ± 23 months and that 25% of the molecular weight was lost after 120 ± 15 months of implantation. Theoretical models of degradation are discussed. The authors state that this rate of degradation does not put patients who have these prostheses at risk, but it does indicate that additional work is needed to improve this material.

Two very timely papers reported on the *in vivo* degradation of polyurethane. Szycher and McArthur compared the surface fissuring of two different polyurethanes with different hardnesses used in pacemaker lead insulation. Their examination showed surface fissures at points of high stress such as ligature sights and high stress areas introduced by the manufacturing processes used in these devices. They hypothesize that the surface fissures may be due to *in vivo* oxidation of the polyether chain. They recommend that ligature stress be lowered by use of silicone anchoring sleeves, that manufacturing processes be controlled to reduce stresses, and that higher durometer polyurethanes be used that are less susceptible to stress-induced failures.

Parins et al reported on animal testing done in support of pre-clinical investigations of polyurethane leads. During the early phase of this investigation, unexpected surface cracks were observed leading to an expanded test program. They reported no obvious correlation between surface cracking and mechanical properties, although such evidence may have been hidden by the inherent scatter in the data. Their examination confirmed the relationship between stress and cracking reported by the previous authors. They conclude similarly that the successful performance of this polyurethane depends on proper use.

In a change from most of the previous papers that reported the negative aspects of biodegradation, there were two papers presented on materials that made positive use of this phenomenon. Dunn, Casper, and Cowsar described a biodegradable composite material they have developed that will be useful in reconstructive surgery, particularly maxillofacial reconstruction. The composite is a laminate of PLA sheets with fiber-reinforced PLA sheets. The fibers used were either carbon or ceramic. The resulting composite has initial mechanical properties very similar to those of bone but degrades *in vivo* over time to prevent stress protection atrophy and alleviate the necessity for later removal of the device.

McKellop and Clarke have extensive experience at wear testing of total hip joint components. In the paper presented here, they report on the testing of titanium alloy hips from three different manufacturers and compare the results from those devices to similar tests on steel or cobalt hips from the same three sources. One of the sets of titanium hips had been given a special nitriding treatment that gave these devices a harder surface. Since previous data reported by several authors questioned the wear characteristics of titanium alloy hips, this

carefully controlled and comprehensive study is of much interest. The results reported indicated that there was no significant difference in the wear rates of the polyethylene associated with any of the devices tested except the surface hardened titanium alloy devices that showed lower wear rates. All of the wear rates reported were within the ranges observed clinically.

Lemons has given an excellent review of the history, results of animal testing, and human clinical applications of tricalcium phosphate ceramics. This material is intended as a treatment for bone lesions and should biodegrade leaving a natural tissue repair.

Certainly, loosening of total hip stems within the PMMA cement bed is a clinically significant problem. Ebramzadeh et al report that the literature indicates up to 40% incidence of cemented stem loosening with more cases possibly undiagnosed due to the inability of radiographs to reveal small gaps. In the work reported here, they developed new techniques to measure bone cement strains in a model bone. An interesting result of the testing was that proximally where the cement strains were the highest the strains reduced by as much as 73% after about 4 million loading cycles. This is evidence of creep within the cement layer. Understanding this phenomenon is important in designing prostheses that reduce cement stresses.

Two papers on total joint retrieval analysis are included in the book. One paper reports on retrieved prostheses from a study by the Mid American Joint Replacement Institute, University of Missouri-Kansas City School of Medicine by Hood. The paper states that the goal of implant retrieval programs is to identify specific implant problems relating to design, material, installation, patient weight, and other factors. Cataloging this information provides a base of information for improving total joint prostheses. Guidelines are given for collecting data, examining, and storing the retrieved implants. Problems noted were wear in metal-to-metal joints, fracture of the metal stems resulting from localized stress due to cement loosening, or improper placement for carrying the load, or all. The UHMW polyethylene components are subject to wear and fracture. Implantation time and body weight were discussed.

Wright, Burstein, and Bartel of the Hospital for Special Surgery, New York, NY, reported on a six year experience of total joint retrieval and analysis. There are common elements in the approach and conclusions of the two studies. This work had as one purpose to relate material type and design to implant mechanical performance. Retrieved components were cleaned, examined, and classified according to specific procedures including a review of the patient's medical record. A total of 1082 total joint components were analyzed. These were taken from patients with weights ranging from 35.4 to 112.5 kg with a mean weight of 79 kg, and ages ranging from 26 to 84 with a mean age of 64 years. The mechanism given for metal failure was fatigue with the fracture location varying with prosthesis design. Wear and deformation of polyethylene were observed. Articulating surfaces of polyethylene exhibited damage due to delamination and abrasion.

The long-term performance of polyethylene based on these retrieved analyses is questionable, and the possibility of optimizing UHMW polyethylene performance with different designs should be investigated. There are specific descriptions of a number of components and their failures in both the retrieval papers.

The subject of developing performance standards was addressed by Mayor who described design standards as a method of assuring the performance of a material or device based on measurable parameters. These design standards provide predictability but restrict innovation. The performance standard would provide assurance of predictable use without constraining imaginative solutions to problems. Writing performance standards will be more difficult, will press the state of the art, and will require test methods not yet developed. In spite of the enormity of the task, the author suggests that performance standards are the direction in which standards writing should be moving. An illustration of a performance standard in another field is given and additional information is provided to help the reader understand performance standards.

The paper by Piehler on pluralistic medical device risk management also cites the need for performance standards. Failure of a device is defined as the patient not being able to recover to the expected level or having to undergo additional surgery to correct the problem. Standards, either voluntary or mandatory, are used in regulation or litigation. Although a number of factors such as clinical procedure, patient misuse, unfavorable tissue response, etc. contribute to device failure, only the device itself is covered in the Medical Device Amendments of 1976. A plan is presented for the development of performance standards in which the private sector would carry out the development of the standards. The standards would meet the needs of the Food and Drug Administration (FDA) and the criteria of a voluntary consensus organization. The author discusses the marketplace incentive for the development of the performance standards and indicates that the adversarial tension between the FDA and the private sector would disappear.

Anna C. Fraker

National Bureau of Standards Washington, DC
20234; symposium chairman and editor.

Charles D. Griffin

Carbomedics, Inc. Austin, TX 78752; symposium chairman and editor.