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Overview

Since portions of the human body are composite structures, the progression towards the use of composite materials for application in the human body is natural. Because the properties of materials and interfaces in the body are unique, it is difficult to duplicate these properties or even to accommodate them without considering the potential advantages of engineered composite materials custom tailored mechanical properties. The bulk of papers in this symposium are concerned with orthopaedic applications. This is not unusual for three reasons: (1) the ASTM Committee F-4 on Surgical Implants that sponsored this symposium is a primary source worldwide for standards related to orthopaedic materials and devices; (2) the market for orthopaedic products is well-established and materials conscious; and (3) the replacement of the unique properties of bone-in-bone interfaces appears to be an excellent application for structural composites. Despite the optimism about the potential of orthopaedic applications of composite, the emphasis of many of these papers is caution. Orthopaedic prosthetic devices are nonredundant systems that are not easily replaced. Failure of a single component in a system or a material could lead to loss of function of the device and require a revision operation. Consequently, many of the test methods relate to the long-term viability of the composite materials and devices.

The two papers by Maharaj and Jamison highlight two potential problems for a stemmed femoral total hip replacement fabricated from structural composites. The paper entitled, "Intraoperative Impact: Characterization and Laboratory Simulation on Composite Hip Prostheses," covers potential effects of impacts that are typical of surgical implantation techniques for femoral stems. The effect of these impact loads must be considered in terms of the potential damage they may cause to the composite material. Thus, impact loading should be a part of a representative environmental conditioning step, prior to any long life fatigue evaluation of a prosthesis.

The paper, "Creep Testing of a Composite Material Human Hip Prosthesis," points up another problem related to the viscoelastic nature of the polymer matrix of many polymer fiber composites. Under continuing load there can be plastic deformations that occur in the viscoelastic polymeric matrix. Although most of a femoral component in a Total Hip Replacement (THR) is supported by bone that provides additional resistance to creep, the portions of the prosthesis above the bone will never see any additional support, and consequently could be subject to significant amounts of creep. Developing methods to study creep in simulated applications and determining if it represents a problem in long-term application of the material to the total hip prosthesis are significant steps in the design of structural composite material implants. The paper by Humphrey and Gilbertson, "Fatigue Testing of Femoral Hip Prostheses with a Two Beam Simulated Femoral Bone Support Fixture," attempts to find an improved simulation method for the fatigue testing of composite hip prosthesis. One of the potential advantages of a composite THR femoral stem would be to achieve elastic properties closer to those of living bone. Such a low modulus implant, however, severely overburdens many of the fatigue methods currently used to evaluate the long-term fatigue resistance of hip stems. Providing a method to adequately evaluate the long-term fatigue resistance of composite femoral stems is another important obstacle that must be overcome in order to demonstrate long-term safety of a composite femoral THR stem.

The paper by Kovacs, "*In Vitro* Studies on the Electrochemical Behavior of Carbon Fiber Composites," and the paper by Salzstein and Moran, "Stability of Polysulfone Composite Materials in a Lipid Environment," show that biocompatibility must be a two-way street. Not only must the body be able to tolerate the presence of the implant, but the implant materials must be able to survive the environment of the body. The environment of the body is uniquely dynamic and aggressive, in part because of the body's effort to biochemically isolate and/or remove foreign materials. Polymers and polymer composites have not been used extensively in structural applications in the body. These papers cover two different possibilities of human body/composite material interaction that must be evaluated to provide a reasonable level of confidence that a composite material can survive in harmony with the body in a long-term application.

The paper by Cheal, Grierson, Reilly, Sledge, and Spector, "Comparative Study of Carbon Polymer Composite and Titanium Femoral Stems in Dogs Using Computed Tomography," covers yet another important viewpoint of testing that must be performed to demonstrate the safety and potential effectiveness of composite materials in orthopaedic application. Animal studies have long been used to evaluate clinical concepts prior to use in the human body. The ability to use computed tomography (CT) to evaluate the response of bone to more elastic prostheses will permit more efficient use of animal studies in evaluating composite materials.

Since composite materials are custom engineered, theoretical analysis is an important stage in the design of the composite material. In the paper by Latour and Zhang, "The Effect of Interfacial Bonding Upon Compressive Strength and Fracture Energy of Carbon Fiber Reinforced Polymer (CFRP) Composite: A Theoretical Investigation," it is shown that micromechanical modeling of the material and its response to the mechanical load environment in the body is an important step in the design of an appropriate composite material for human body application. The paper by Liao and Reifsnider, "A Life Prediction Model for Fatigue Loaded Composite Femoral Prosthesis," demonstrates an important micro-mechanical modeling technique that can be used to evaluate the unique cumulative damage that can occur with a composite material, and its potential effect on the long-term performance of a composite prosthesis.

The paper by Zimmerman, Boone, Scalzo, and Parsons, "A Mechanical and Histological Analysis of the Bonding of Bone to Hydroxylapatite/Polymer Composite Coatings," attempts to evaluate one of the unique problems that may occur with composite prostheses, that of attachment to the tissue. In order for a composite structural prosthesis to perform as a natural part of the composite structure of the body, it must have some form of attachment to the human body. In some applications, simple direct apposition may not be sufficient and creation of an attachment interface may be necessary. Many of the methods that are used for attachment of metallic prostheses may not be suitable for composite prostheses, and consequently, new methods of attachment must be developed. This paper discusses some of the concerns that must be addressed in evaluating potential attachment interfaces both biologically and mechanically.

The paper by Hawkins, Zimmerman, Parsons, Langrana, and Lee, "Environmental Effect on a Thermal Plastic Elastomer (TPE) for Use in a Composite Intervertebral Disk Spacer," covers a unique definition of composite material in a quasi-structural application. This composite prosthesis is actually a polymer/polymer composite and represents an entirely different mechanical property problem than would be addressed by most other orthopaedic composite prostheses. The ability of the human spinal disk to repeatedly deform and recover in the human body, is an extremely difficult application for an artificial material to mimic. This paper addresses concerns and problems that must be dealt with in such an application.

The paper by Vaidyanathan, Vaidyanathan, and Waknine, "Characterization and Optimization of Small Particle Dental Composites," covers an area of composite material use in the body that is already significant. The use of composite materials in dental fillings is growing, and despite the fact that replacement of fillings in teeth is not a major operation, the long-term viability of such composite materials is important for optimization of those materials. The paper covers many of the unique mechanical and environmental tests and considerations that must be made in evaluating such materials.

Russell D. Jamison,
Smith & Nephew Richards, Inc.; Memphis, TN; symposium chairman.

Leslie N. Gilbertson
Zimmer, Inc; Warsaw, IN; symposium co-chairman.