Overview

The assembly of orthopedic prosthetic joint implants from modular components improves the options of the surgeon in the operating room, reduces the inventory of sizes that must be maintained in the hospital and by the manufacturer (distributor), and allows the surgeon to tailor the device to the situation confronted on the operating table. Modularity of implants also presents some interesting problems to the device designer and to the treatment of patients after surgery. In November 1995, ASTM Committee F4, Medical and Surgical Devices and Materials, conducted a symposium on the subject of Modularity of Orthopedic Implants. The objectives of the symposium were to define the knowledge base at the time and provide guidance to the members of the committee who were invested in the development of standards for the measurement of the properties of these devices. The symposium papers published here explore the clinical utility of these devices, the problems presented clinically, and the analytical tools, developed by engineers in manufacturing firms and academic institutions, used to evaluate the devices.

Clinical Relevance

Initially, five papers were scheduled in this session and presented at the symposium. Through several circumstances, only one of these is published in this STP. These authors addressed the rationale, including pros and cons, for using modular design in hip and knee prostheses and in soft tissue attachment using bone anchors. In the only paper of the group published here, Joseph Zuckerman presented a very complete survey of the clinical literature rerlated to total shoulder arthoplasty (TSA) and the introduction of modular designs for TSAs. While acknowledging that the introduction of modular TSAs is relatively new and, therefore, the longevity of the repaired joints is in some question, the early results are very supportive of the modularity concept.

One paper presented as part of this session, but not published in this volume, focused on the general process by which ASTM develops standards. We wish to thank Jack Lemons for sharing his thoughts on the process and mechanics of standards development, and for emphasizing the need for attending the symposium as well as the need for readers of this volume to participate in the development of consenus standards.

Issues of Concern

The issues of concern expressed by the authors of the papers in this session were very wide-ranging. Stuart Goodman reported on a revision series of acetabular components in which no correlation between modularity and the biological indicators of bone remodeling was identified but reported that, at revision surgery, many of the cellular components and cytokines associated with loosening and osteolysis were present. Urban et al. further developed this thought by examining the solid products of corrosion that devlop in modular head-femoral stem joints and expressing concern about the kinetics of these degradation products. Gilbert and Jacobs reviewed several test methods they developed to evaluate mechanically-assisted crevice corrosion and compared test results with corrosion found on retrieved head/stem combinations of several metal alloys. Shea et al. completed the discussion of biological concerns by reporting on the generation of polyethylene particles at the several interfaces in a design of modular acetabular cups. They note that considerable work has been done to control particle generation at the femoral head/acetabular liner interface, but

that attention must be paid to reduction of motion at the other interfaces. Finally, Calès noted that understanding and controlling the manufacturing methods of these devices (specifically, marking ceramic femoral heads) is important to ensure that these methods do not contribute to the initiation of failure mechanisms of the arthroplasty device.

State of the Art in Properties Testing

The papers in this session were almost evenly divided between discussions of the mechanical testing of modular devices and discussions of the various corrosion mechanisms that seem to be acting upon them.

Heim reported on a comparative study of the bending fatigue resistance of four modular hip designs. Lambert and McLean developed a method to study the dynamic fixation in torsion of the polymer liner within the acetabular component, and Fosco and Buchanan reported on test methods to study the push-out and lever-out forces of these components. Kirkpatrick studied the static strength of the polymer articulating surface within the tibial tray of modular total knee systems and Anthony reported on a fatigue test for the tibial component. Schmidt described work to assess the raltionship between the impaction force of a ball on a Morse taper stem and the subsequent disassembly forces. Richter studied the relationship between the ductility of the metal stem and the load-carrying capacity of a ceramic ball mated to it. Naesguthe demonstrated the apparent difficulty in manufacturing matching tapers as would be needed to optimize joint load-carrying performance. These papers constitute a starting point for discussion of testing methods for modular hip and knee joints and should be considered by developers of device standards.

Four papers were presented on fretting corrosion mechanisms and aspects of corrosion-testing of modular hip prostheses. The papers by Bhambri et al., Goldberg et al., McLean and Lambert, and Brown et al. present an internally consistent argument for development of a fretting corrosion requirement for these devices. Special attention is given to the mixed-metal couples created by the use of dissimilar alloys in the stem and head of the prosthesis. A considerable body of data is presented with which to begin to define the testing environment, testing frequency, and loading waveform for such a test method.

Significance and Future Work

The symposium showed the clear clinical benefits related to this type of orthopedic joint and identified no new problems with their use that had not been associated with earlier designs of arthoplasty devices. While the magnitudes of some of these corrosion problems remains unquantified and may, at a later date, present a reason to alter the scientific wisdom expressed here, no extreme actions to change current medical practice currently seem justified.

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