Modularity of Orthopedic Implants

Donald E. Marlowe, Jack E. Parr,

and Michael B. Mayor, editors

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Foreword

This publication, *Modularity of Orthopedic Implants,* contains papers presented at the Symposium on Modularity of Orthopedic Implants held 8 November 1995 in Norfolk, VA. The symposium was sponsored by ASTM Committee F4 on Medical and Surgical Materials and Devices. Donald E. Marlowe, of the FDA Center for Devices and Radiological Health in Rockville, MD; Jack E. Parr, with Wright Medical Technologies in Memphis, TN; and Michael B. Mayor, with the Dartmouth Hitchcock Medical Center in Lebanon, NH, presided as symposium chairmen and are editors of the resulting publication.

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STATE OF THE ART IN PROPERTIES TESTING II

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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Clinical Relevance

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A REVIEW OF THE USE OF MODULARITY IN TOTAL SHOULDER ARTHROPLASTY

REFERENCE: Zuckerman, J. D., Cavallo, R.J., and Kummer, F. J., **"A Review of the Use of Modularity in Total Shoulder Arthroplasty,"** *Modularity of Orthopedic Implants, ASTM STP 1301,* Donald E. Marlowe, Jack E. Parr, and Michael B. Mayor, Eds., American Society for Testing and Materials, 1997.

ABSTRACT: Modularity is a recent advance in total shoulder arthroplasty (TSA). The use of a separate head-stem combination permits intraoperative adjustment of soft tissue tension necessary for successful TSA. Modular glenoid components allow auxiliary fixation by various coatings or screws. Short-term clinical results (<5 years) indicate that the results of modular TSA are equivalent to those of monolithic TSA. Several cases of head-stem disassociation have been observed. It is possible that taper corrosion and polyethylene insert failure could occur in the long term, as has been seen with modular hip replacement.

KEYWORDS: modularity, shoulder arthroplasty, humeral prosthesis, glenoid prosthesis

INTRODUCTION

The first shoulder arthroplasty was performed by the French surgeon Pean in 1893 for a proximal humerus destroyed by tuberculosis [1,2]. The modern era of shoulder arthroplasty began in the mid-1950s when Neer published the preliminary results of 12 patients treated with a proximal humeral replacement [3]. Because his results were far superior to resection arthroplasty, he concluded with guarded optimism that the shoulder arthroplasty would wear better than its counterpart in the weight bearing hip. In 1972, Neer and his

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colleagues designed three different types of fixed-fulcrum prostheses in an effort to eliminate the need for the rotator cuff. The failure of this design was attributed to the increased shear stresses imparted to the glenoid component as a result of the unopposed superior forces produced by deltoid contracture. Other authors confirmed the high rates of mechanical failure with different constrained designs [4-6], and this technique was abandoned.

In 1973, Neer redesigned the humeral prosthesis so that it conformed to the radius of curvature of a newly designed polyethylene glenoid component. This became one of the first nonconstrained total shoulder arthroplasties (TSA). It was designed to (1) limit the amount of bone removed to preserve soft tissue attachments; (2) maintain near-anatomical design to permit the maximum return of motion; (3) avoid mechanical impingement that might lead to mechanical failure; and (4) emphasize the importance of reconstruction of the surrounding soft tissue structures [7]. The success of this implant has been well documented [8,9], but has not deterred the development of alternative prosthetic designs.

Currently, approximately 10,000 shoulder arthroplasties are performed annually in the United States. Despite the fact that this figure has risen exponentially over the years, it remains far less than the half-million total hip and total knee arthroplasties performed annually [10]. Similar to other total joint arthroplasties, replacement of the shoulder can be expected to improve function and dramatically alleviate pain for the vast majority of patients. Early on, however, Neer recognized the shoulder as a unique functional unit, which distinguished it from the hip and knee. The stability of these joints is largely dependent on either the bony congruity or the supporting ligaments, respectively [7]. In the shoulder, however, the shallow glenoid and loose ligamentous support (static stabilizers) provide far less inherent stability but permit much greater range of motion. The supporting musculature (dynamic stabilizers) become critically important for both stability and motion. In fact, the functional success of TSA is largely determined by soft tissue preservation, restoration, and rehabilitation. These considerations make TSA one of the most technically demanding joint replacement procedures performed by the orthopaedic surgeon [2]. More recently, the development of component modularity in TSA has increased the versatility of the implants while at the same time adding new decision-making aspects to the procedure. The purpose of this paper is to provide the recent information on the use of modularity in TSA.

BIOMECHANICS

The glenohumeral joint has the greatest range of motion of all joints in the human body. To achieve this motion, it has evolved with minimal bony constraint. Although the ligaments contribute to limit translation, their contribution to stability is less than in the hip and knee. Stability is provided mainly by the dynamic stabilizers.

Bony architecture in the shoulder affords little inherent stability and in fact may predispose to instability, as conformity and contact area are low relative to other joints. In a cadaveric study by Friedman et al. [31], only 21% of specimens had a congruent relation-

ship between the humeral head and glenoid. In addition, 76% were found to have a humeral head with a smaller radius of curvature than the glenoid. Not only is the radius of curvature different, but the surface area for articulation is markedly dissimilar. The surface area of the humeral head is 2 to 4 times greater than that of the glenoid, and the diameter of the head is nearly twice that of the glenoid [32]. The result is that only a small portion of the humeral head area is in contact with the glenoid fossa at a given time. More importantly, this contact area decreases with certain glenohumeral positions, resulting in a greater force per unit area (stress) across the joint [31,33]. These findings are in contradistinction to those for the hip, where bony congruity is high and is the primary factor for stability. In addition, increased congruity in the hip leads to increased contact area and a more even stress distribution. Studies have determined that the forces across the shoulder are approximately 0.89 times body weight [31], whereas those across the hip are in excess of 3 to 6 times body weight [34]. However, use of the arm with activities of daily living and carrying objects greatly increases these forces [29] and can probably approach those across the hip. This results in higher and more concentrated stresses (force/area) and has implications for TSR longevity, particularly wear and loosening of the glenoid component.

The dynamics of forces acting across the shoulder are also different from those at the hip. Although the position of the glenoid fossa remains relatively constant throughout most of the arc of motion, the shoulder joint does not act strictly as a ball-and-socket articulation. Unlike the hip, at the extremes of motion humeral head rotation is coupled with translation [32]. Studies have found that the rotator cuff is not responsible for these coupled motions and that capsuloligamentous restraints are more likely involved [35]. This again emphasizes the importance of proper soft tissue reconstruction and tensioning in TSA and the potential benefits achieved by a modular design.

HISTORY OF MODULAR JOINT ARTHROPLASTY

The advent of modularity in TSA is a relatively recent event that followed the successful use of modularity in total hip arthroplasty. As expected, there are much more data available on the results of modularity in total hip procedures. For this reason, and because of its applicability to modularity in TSA, we first discuss the relevant issues related to modularity in total hip arthroplasty.

The evolution toward modular prostheses began in 1970, when Harris developed the metal-backed acetabular component [11]. His goal was to replace the bearing insert without disturbing the primary components. The orthopaedic community was slow to accept "modularity," and it was not until the 1980s that modular femoral components became available [12]. These provided a variety of head and neck combinations, which helped reduce hospital inventory while maintaining a broad spectrum of intraoperative versatility [13]. Additional advantages included enhanced exposure during revision operations as a result of modular head removal and the ability to adjust neck length and head diameter for optimal soft tissue tensioning [14,15]. Biomechanically, modularity also provided the

opportunity to create improved mixed-alloy systems with different material and mechanical properties. The selection of a rigid, wear-resistant material for the head along with a more flexible material for the stem could offer significant advantages over the use of a single, homogeneous implant [13,16,17]. For example, titanium alloy has been advocated for porous coated uncemented stems because of its relatively low modulus, while cobalt-chrome alloy is favored for the head because of its superior wear properties [18].

The initial success of modular hip prostheses, as defined by the increased versatility, led to the development of additional modularity options. These included the ability independently to size the metaphysis and diaphysis as well as to adjust anteversion. This unfortunately occurred concomitantly with a growing body of evidence of engineering problems with the original modularity options (head-neck interface and two-piece acetabular cup), causing concern that clinical failure could result [19]. It became evident that there were many questions to be answered with respect to the intermediate and long-term performance of modular replacement systems: (1) What is the risk of dissociation of the components? (2) Will micromotion result in mechanical wear (fretting) at the interface? (3) Will corrosion occur at the interface between mixed alloy systems? (4) Will mechanical damage or corrosion increase the risk of long-term failure at the taper connection? and (5) Will mechanical damage or corrosion increase the risk of loosening at the bone-prosthesis or bone-cement interfaces [14]?

The problems associated with modular prostheses can essentially be divided into three categories: (1) structural/engineering; (2) chemical/biological; and (3) technical/intraoperative. In some instances, the concerns are theoretical and have not been linked to clinical failure. The technical problems are the easiest to overcome and simply require careful attention to detail by the surgeon and staff. The surgeon should be responsible for the proper handling of taper components prior to implantation to ensure optimum mechanical integrity and hence clinical performance. Taper interfaces perform better when they are properly cleaned and dried prior to engagement [20,21]. Also, large impact assembly loads optimize locking at the Morse-taper interface [19,22].

The structural/engineering and chemical/biological issues in modular components can be largely addressed with improved quality control standards by manufacturers and better design tolerances to prevent motion at component interfaces [23]. In addition, it has been recommended that modular connections be restricted to areas where bending and torsional loads are not excessive. Design improvements have already been made for acetabular implants with regard to locking strength, polyethylene liner congruency with the metal shell, and polyethylene thickness [19]. Head-neck taper interfaces have been improved by shrink-fit designs that decrease micromotion and fretting and silicone sealants that help prevent ingress of fluid at the taper interface [16].

MODULARITY IN TOTAL SHOULDER ARTHROPLASTY

For many years the most widely used shoulder replacement system was Neer's nonmodular design. With the knowledge gained from early successes with modular total hip

arthroplasty, however, the potential benefits of modularity were quickly extended to the area of TSA. The first modular shoulder systems were developed in the mid-1980s for the purpose of enhancing intraoperative versatility and improving visualization during revision procedures [24].

As reports on the long-term results of TSA were published, critical differences with total hip replacement began to emerge. Careful surgical technique for the placement of components and, especially, soft tissue tensioning were clearly linked to the long-term success or failure of TSA. The impact of a deficient rotator cuff (which has no counterpart in the hip) on glenoid component loosening has been reported by many authors [25,26]. Rotator cuff deficiency results in proximal migration and eccentric loading on the superior aspect of the glenoid component. Consequently, a "rocking horse" motion occurs that leads to glenoid loosening. The cited studies and others made it apparent that the success of a TSA was critically dependent on the integrity and balance of the surrounding soft tissue structures [1]. In theory, modular systems enhance the surgeon's ability to optimize soft tissue balancing and function compared with traditional, nonmodular designs. Modularity of the humeral component facilitates soft tissue tensioning and centralization of the humeral head within the rotator cuff [24,27,28]. This, in turn, helps to minimize eccentric loading of the glenoid component, which may ultimately decrease the incidence of glenoid loosening [1]. In addition, optimizing soft tissue tension by modularity also aids in achieving a stable articulation [29,30].

MODULAR SHOULDER DESIGN

Humeral stems can be fabricated from cobalt-chromium alloy or titanium alloy and have a distal cylindrical section with a rectangular proximal section or proximal fins to increase torsional stability within the humeral canal (Fig. 1). Stems can be press-fit, cemented, porous, or coated with hydroxyapatite (HA) for fixation. The taper can be located either on the head or stem (Fig. 2). Placing the taper on the head increases accessibility during surgery and enables designs in which the head can be offset by eccentric taper placement to duplicate normal anatomical orientation (Fig. 3). The taper is smaller than those in THR and has been augmented with adjacent pegs or a separate screw to increase stability (Fig. 4).

Heads are usually cobalt-chromium (one design uses nitrogen implanted titanium alloy) and hemispherical, although at least one design is ellipsoidal. A variety of head radii (typically three) or neck lengths (constant head radius) permits intraoperative soft tissue tensioning. Anteversion can also be designed into the head to increase stability and minimize dislocation in cases with excessive retroversion.

Modular glenoid components consist of an outer metal shell (titanium alloy) with a polyethylene insert (typically three sizes) and were originally developed for cementless fixation—e.g., porous or HA coatings or the use of several screws. Some designs offer several thicknesses of inserts to facilitate soft tissue balance without altering the center of rotation to the extent it would be if accomplished by solely increasing head size. Some

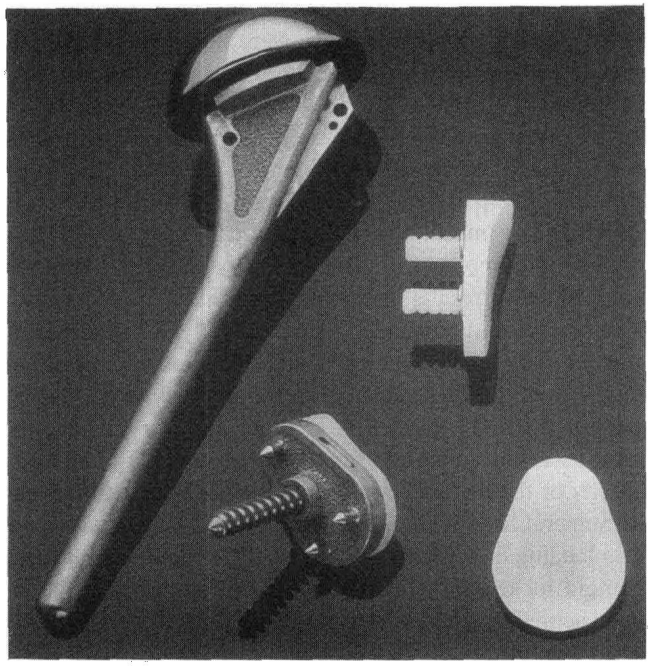

Fig. 1. A typical modular shoulder system. The head is assembled on the humeral shaft; the pad at the top of the stem is for ingrowth fixation. Two alternative glenoid components are shown in side view, one metal-backed and one all-polyethylene; the bearing surface for each is the polyethylene facing shown in lateral view (lower right).

computer modeling studies suggest that an all-polyethylene glenoid component may transfer stress in a more physiologic manner [39]. As a result, surgeons are more inclined to insert nonmodular polyethylene glenoid components in an effort to reduce the risk of glenoid loosening which is the most common cause for a revision complicating TSA.

CLINICAL RESULTS OF MODULAR SHOULDER ARTHROPLASTY

The efficacy of modularity in shoulder arthroplasty must be evaluated in comparison to the clinical results of the nonmodular designs. The most commonly used nonmodular system is the one designed by Neer, and thus many of the clinical results are for the use of this system. Overall, the success rate has been encouraging: over 90% of patients experience good or excellent results in two- to nine-year follow-up [7,9,40]. Pain relief has been reported as excellent in all patient groups undergoing the procedure, but return to function has generally correlated with the integrity of the rotator cuff. It is not surprising, then, that osteoarthritics undergoing TSA have obtained the best functional results

Fig. 2. Offset tapers, which can be used to control head position. (Left) Typical modular head; (right) this head can be "dialed" to the desired degree of numerical translation (the holes on the underside lock with a peg on the humeral stem).

[41]. The rotator cuff in these patients is almost invariably intact, with only 5% of patients having full-thickness tears. Rheumatoid arthritis patients, on the other hand, achieve less dramatic functional gains, since up to 75% will have abnormal rotator cuffs and 20–35% will have full-thickness tears [42].

The clinical results of TSA were recently summarized from 23 series (involving 1459 shoulders) reported from 1982 to 1992 [41]. The incidence of complications was found to be 14% with a minimum two-year follow-up. These included (in order of decreasing frequency): (1) instability (0–22%); (2) rotator cuff tear (1–13%); (3) ectopic ossification (12–40%, rarely clinically significant); (4) glenoid loosening (2% clinical loosening, 30–90% radiolucent lines); (5) intraoperative fracture (<2%); (6) nerve injury (<1%); (7) infection (<1%); and (8) humeral stem loosening (<1%). Implant longevity with nonmodular TSA designs compares favorably with that for total hip arthroplasty patients; revision rates have been approximately 11% at 10 years postoperatively. The most common causes for revision include (1) glenoid loosening; (2) instability; and (3) rotator cuff tearing. These results are from short- and intermediate-range follow-up studies; there are not yet many long-term studies [2]. Torchia et al. [43] reported the results of a series of cases with a mean follow-up of 12.2 years using the Neer prosthesis, found a probability of