Modularity of Prosthetic Implants

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Abstract

The vast majority of total-joint-replacement components currently utilized are modular to some degree. Modularity reduces inventory and increases the surgeon's options in both primary and revision total-joint arthroplasty. Use of a modular interface, however, increases the risk of fretting, wear debris, and dissociation and mismatching of components. The use of modular heads in total hip replacement is firmly established. The occurrence of corrosion and fretting has been recognized, and most manufacturers have improved the quality of the interface to minimize these problems. Modular polyethylene liners also offer advantages, particularly in revision procedures, where the option of additional screw fixation remains important. Many uncemented acetabular components are inserted without screws, which may generate renewed interest in one-piece factory-preassembled components. The conformity, locking mechanism, and nonarticular interface of modular acetabular components have all been studied and improved. Modular tibial components offer additional flexibility in the performance of total knee replacement but introduce the risk of dissociation and increased polyethylene wear; in revision procedures, modularity provides a valuable option for dealing with bone loss and an additional method of fixation by means of press-fit stems. Modular humeral components offer a significant advantage with limited apparent risk; however, longer clinical experience is required to assess potential problems.

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A modular total-joint-replacement component is generally defined as one that the surgeon assembles at the time of implantation. Two-piece components were originally designed to allow replacement of the polyethylene liner or to provide a metal backing, which theoretically improves stress distribution. Later, a metal backing became necessary to provide a metal surface for porous coating. With the advent of uncemented components, a dramatic increase in the number of sizes in various implant systems was required, since a press fit must provide initial stability. At the same time, modularity allowed a major decrease in the inventory required to offer a wide range of options. However, there is no evidence to suggest that the decrease in inventory has resulted in cost savings; the increasing use of modular components has, in fact, coincided with significant increases in prosthetic costs.

The widespread use of uncemented total-joint-replacement components has paralleled the increasing modularity of the components, but there has been a concomitant increase in the incidence and extent of bone lysis, the rate of polyethylene wear, and the generation of particulate debris. It is not yet certain to what extent the modularity of these components contributes to these problems.

In this article I will review the rationale for the application of modularity to various total-joint-replacement components, the established and potential benefits, and the known and potential complications. Optimal design features of modular components will be suggested on the basis of the current state of knowledge.

Total Hip Replacement

Acetabular Components

The concept of a modular two-piece acetabular component was introduced over 20 years ago.[1] The original objective was the ability to replace the liner without disrupting the prosthesis-bone interface should excessive wear occur over time. Another anticipated advantage was improved stress distribution in the subchondral bone of the pelvis as predicted by finite-element models. Subsequent clinical reports have failed to show an advantage of cemented metal-backed acetabular components compared with all-polyethylene components as measured by the incidence of loosening or the development of radiographic lucent lines. Metal backing is necessary, however, to provide a surface for porous coating. The loosening

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and revision rates of porous-coated components have at least equaled those of cemented primary acetabular components during surveillance periods of 5 to 8 years. In the revision situation, the uncemented acetabular components have generally outperformed cemented revision components in terms of the incidence of loosening and re-revision.

In addition to promising clinical results, the modularity of porous-coated metal-backed acetabular components has other advantages. Many of the metal shells have holes that provide the option of screw placement for adjunctive screw fixation. Histologic analysis of early retrieved porous-coated acetabular components has indicated that more bone ingrowth was present when adjunctive fixation was utilized.[2] With the recent practice of underreaming the acetabulum by 2 to 4 mm, similar degrees of stability have been achieved without screw fixation. Component modularity continues to offer the advantage of allowing judgment of the fit through the screw holes prior to insertion of the polyethylene liner. Although underreaming may provide the stability afforded by a tight peripheral rim fit, it does not ensure direct bone contact over the dome of the component. The importance of this contact is not certain, but it does seem desirable in terms of increasing the likelihood of more uniform bone ingrowth.

Another potential advantage of a modular acetabular component is interchangeability of liners. Once the metal shell is impacted, a variety of liners can be selected on the basis of trial reduction and tests of the stability and range of motion. At least one manufacturer offers the option of a modular constrained liner.[3] Some surgeons attempt to improve stability by utilizing an offset liner rotated into a position thought to improve stability. It is unwise, however, to rely totally on such a modular insert for stability. It is preferable in most instances to reposition the metal shell into a more stable orientation. Having done this, however, a modular shell affords the ability to place screws through the shell for additional stability, which is probably advisable in such a circumstance.

The ability to exchange a liner years after insertion because of excessive wear is an occasional advantage. In most cases, however, simple liner exchange is not possible. Often, either the shell has loosened in conjunction with the polyethylene wear or there has been sufficient damage to the locking mechanism or the shell itself to necessitate revision of the entire acetabular component.[4]

In recent years it has become apparent that there are a number of potential complications associated with the use of modular acetabular components. The first is liner dislodgment. A number of cases have been reported, and at least one component has been removed from the market because of this complication. Liner dislodgment has also been reported with porous-coated acetabular components assembled at the factory, although many more cases have occurred following intraoperative assembly. This complication occurs by means of several mechanisms. Failure of a locking mechanism accounts for many cases (Fig. 1). In these instances, the symptoms are often insidious and are similar to those of subluxation. Patients may hear audible clicking or popping, which is due to contact between the metal shell and the femoral head. Because the diagnosis may be delayed, the metal shell may be extensively damaged by the time revision is undertaken (Fig. 2).

Liners may also be levered out by a single event. Liner dissociation

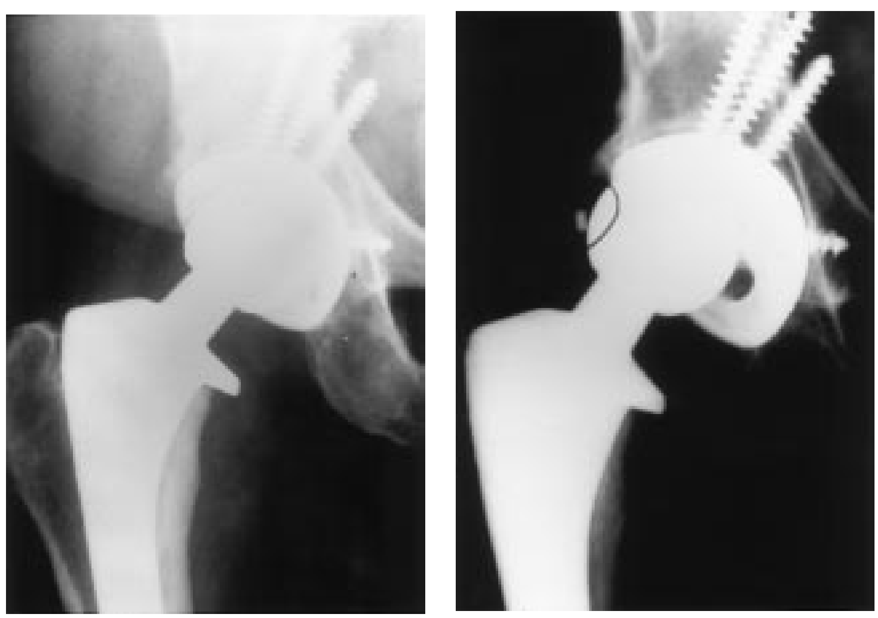

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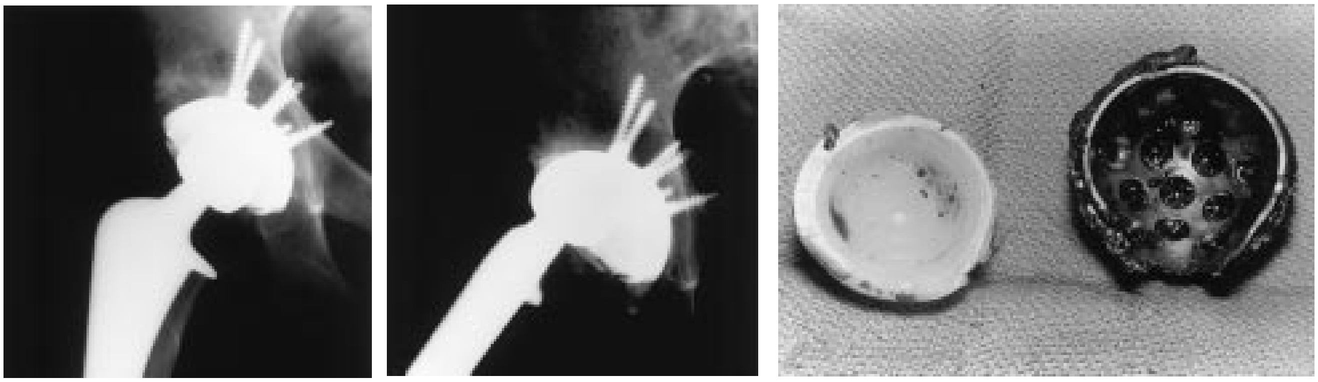
Fig. 1 **A,** Radiograph of hip prior to liner dislodgment. **B,** Appearance after liner dislodgment with broken locking pin.



A B C

Fig. 2 **A,** Postoperative radiograph of right hip. **B,** After liner dislodgment, the patient had symptoms of subluxation and heard popping and clicking. **C,** The metal shell was extensively damaged, necessitating revision of the acetabular shell as well as the liner.

has been reported, for instance, following reduction of a dislocation. The security of locking mechanisms has been found to be extremely variable, with the force necessary for dissociation ranging from 14.9 to 1,380 lb.[5] Liners can rotate within the metal shell, which can lead to clinical problems without frank dislocation. There have been reports of liners with extended lips rotating within the shell into a position causing impingement on the femoral neck and subsequent recurrent dislocation that necessitates revision.[4] While these dramatic failures are uncommon, they often require surgical intervention.

Of greater concern is the possibility that modular acetabular components may be contributing to the increased polyethylene wear, production of particulate debris, and bone lysis currently being observed (Fig. 3). In recent years, modular acetabular components have been more carefully scrutinized, and a number of design characteristics that predispose to increased wear have been identified. The first is inadequate thickness of the polyethylene. The polyethylene liners of many early modular acetabular components were well below the currently recommended minimum thickness of 6 to 8 mm, with some below 3 mm.[6]

Another concern is whether the modular components are effectively backed with metal. Many polyethylene liners fail to bottom out at physiologic loads, resulting in rim loading and excessively high localized stresses in the polyethylene.[7] Even among the designs that demonstrate congruency, there are concerns about cold flow of polyethylene into screw holes, contact of a congruent liner with a sharp metal spike of a locking mechanism, and abrasion of polyethylene by screw heads, particularly if component settling occurs. When the relative lack of conformity is combined with the empty space for screw holes, the actual surface area supported by metal varies from 25% to 75%.[8]

The concerns about excessive stress and high wear rates on the polyethylene in modular acetabular

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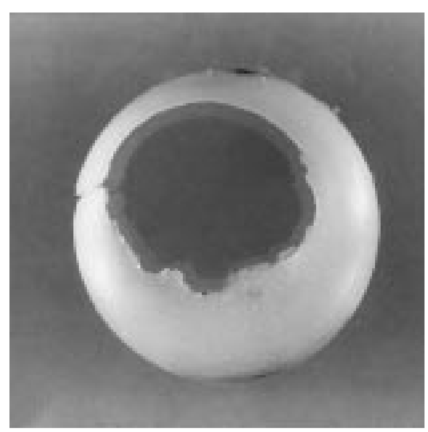


B

Fig. 3 **A,** Radiographic findings of massive lysis in a minimally symptomatic patient. **B,** The thin acetabular liner in this patient had worn through and dissociated.

components are substantiated to a degree by analysis of retrieved specimens. Collier et al[9] found significant wear on the back side of acetabular liners in 20 of 111 specimens examined. Huk et al[10] examined 19 specimens and found damage to the back side in the form of burnishing, surface deformation, and embedding of metal particles in most, raising concerns about back-side wear, creep into screw holes, screw heads digging into the liner, and screw-shell fretting. In two cases acetabular osteolysis was present adjacent to loose screws, and both metal and polyethylene debris were identified in the cystic lesion. This is the basis for the concern that holes in the acetabular components allow access to the cancellous bone of the pelvis, resulting in the destructive lytic cysts that are increasingly observed (Fig. 4).

While modular acetabular components are now known to present certain problems, the promising results with porous-coated uncemented acetabular components in primary cases and particularly in revision cases have been an impetus for continued utilization of these devices. Also, examination of retrieved specimens and laboratory testing suggest that many of these potential problems can be minimized by redesign. Hemispheric cups afford the best chance of obtaining conformity between the porous coating and the acetabular bone as well as between the shell and the liner. Since the shell is now appreciated to represent a wear interface with the back side of the liner, it should be highly conforming as well as smooth and surface treated, like any other weight-bearing surface. The locking mechanism should be strong enough to resist levering out, yet should not present a sharp interface that can itself generate wear debris. Finally, elimination of screw holes is desirable to minimize the risk of debris generation. This should be possible in most primary cases with current press-fit techniques. However, elimination of screw holes places more pressure on the surgeon to obtain good alignment on initial impaction, since there will not be the ability to reposition and reimpact the component and add stability with screw fixation. In revision components, making provision for adjunctive screw fixation is still advisable in many, if not most, cases.

A

B

Fig. 4 **A,** Postoperative radiograph of uncemented total hip replacement with screw fixation of modular acetabular component. **B,** Five years later the patient was minimally symptomatic but had a large cystic lesion in the vicinity of the screw in the ilium. The head appears eccentric in the liner.

Head-Neck Components

Modular heads have a number of advantages, including the ability to combine different materials for the head and the stem, to reduce inventory, and to allow fine-tuning of leg length after the final stem has been implanted. In revision cases in which only an acetabular component is being replaced, a modular head can be removed to assist in exposure, and a head-neck component of a different length can be impacted onto the stem to equalize the leg length. Occasionally, long heads or extension sleeves are utilized to gain stability in patients with soft-tissue laxity or insufficiency. Sciatic nerve palsy has been reported to resolve after changing to a shorter modular head.

Modularity of the head has led to a number of complications. Dissociation of the head has been reported.[4] Often this event follows reduction of a dislocation; therefore, this possibility must be kept in mind when reducing a dislocated total hip after modular total hip replacement. There have also been reports of fracture at the base of a modular trunnion.[8] Corrosion at the head-neck interface is considered to be a contributing factor in these instances.

Another disadvantage associated with modular heads is related to their effect on range of motion. Head modularity requires a neck with a circular cross section, which impinges sooner than devices such as the trapezoidal T-28 system (Zimmer, Warsaw, Ind). Other design elements that further restrict motion include a smaller head, a longer neck length achieved with an external skirt, and a modular head in combination with an eccentric or offset liner.[11] Impingement can result in dislocation, excessive polyethylene wear, and liner dissociation.

A final complication of head and liner modularity is the potential for mismatching components (Fig. 5). The large number of component combinations increases the potential for such a mishap and requires heightened awareness on the part of surgeons utilizing these systems.

Although these complications are uncommon, they frequently necessitate reoperation. As with modular acetabular components, the greater concern is that corrosion products and wear debris generated at the head-neck interface are contributing to the clinical problem of accelerated polyethylene wear and associated lysis.

Collier et al[12] were among the first to study the modular head-neck interface. They identified galvanically induced crevice corrosion in the majority of mixed-metal systems (cobalt-chrome head on titanium trunnion). This was invariably present in components in situ longer than 40 months and was not observed in single-alloy combinations. Cook et al[13] examined over a hundred retrieved components and came to somewhat different conclusions. Wear and corrosion were present in 35% of mixed-alloy components but in only 9% of single-alloy systems. However, the presence and degree of wear and corrosion were not time dependent, as reported by Collier et al. Significant wear and corrosion were seen in less than 2 years in some single-alloy systems and not at all at time periods beyond 5 years in some mixed-alloy components. This observation strongly suggests a problem related to the individual implants rather than an inevitable result of material combination.

Cook et al[14] also undertook in vitro studies to examine the effect of material combinations, surface treatments, and neck length on generation of wear debris by modular head-neck interfaces in a saline environment. The combination of a cobalt-chrome head with a titanium trunnion did not, in itself, lead to increase in wear debris. Every combination of materials caused the generation of millions of particles in the 1- to 2-µm range. The factor most important in increasing the particle count was dimensional mismatch. Roughened and nitrogen-implanted surfaces produced fewer particles, while heads larger than 10 mm produced more particles.

The consensus of a number of investigators is that the surface damage seen at the head-neck taper is initiated by fretting. Fretting has been demonstrated in 100% of test specimens in vitro and in over 50% in vivo.[15] The fretting disrupts the passive oxide layer and thereby increases the potential for crevice development and galvanic corrosion.

A

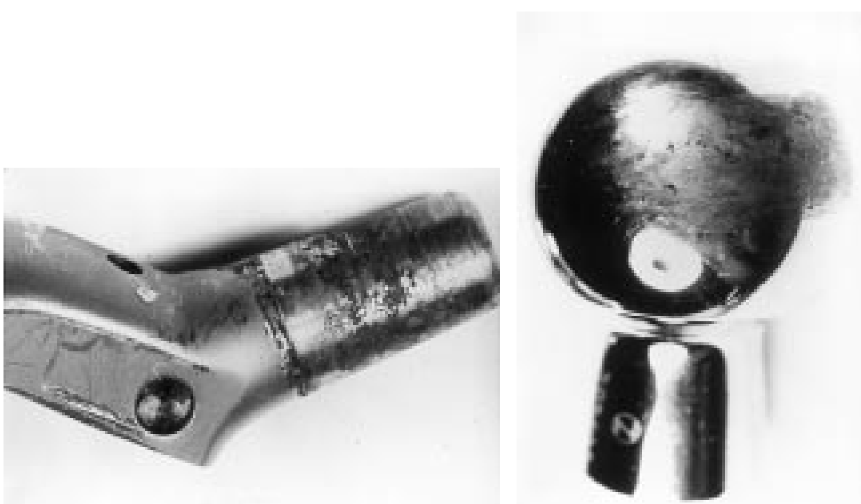
B

Fig. 5 **A,** Postoperative radiograph of a 22-mm liner mismatched with a 26-mm head. **B,** After revision to a 26-mm liner, the head is seated congruently with the acetabular liner.

The number of metallic particles generated at the head-neck interface is orders of magnitude less than the number of polyethylene particles generated by the femoral head articulation with the acetabular liner, yet the clinical significance of these particles is unclear. While fewer in number, the metal particles may act as a third body to accelerate polyethylene wear and / or act synergistically with polyethylene particles to cause bone lysis. Corrosion products from modular head tapers have been demonstrated at the articulating surface of the joint as well as in the capsule and at distant sites of endosteal erosion.[16] While a causal relationship has yet to be established, it remains a reason for concern (Fig. 6).

Modular heads offer distinct advantages, their use is well established, and the vast majority function without any clinically apparent problem. The risk of wear debris, corrosion, and dissociation can be minimized by attention to detail during implantation and by improvements in manufacturing. If the prosthesis is cemented, the head should be impacted with several firm blows on the back table prior to implantation. Forceful blows shortly after cement polymerization can damage the implant-cement interface. Assembly prior to insertion is therefore advisable. When implanting an uncemented stem, the head should be impacted onto the trunnion after implantation of the stem, because the vibration of striking the implant can disrupt the lock of the Morse taper. In either case, extreme care should be taken to keep the interface clean, dry, and free of any debris. Even a fraction of a millimeter of blood can substantially weaken the taper lock and accelerate corrosion and wear. Modular heads from different manufacturers cannot be interchanged, as they all have different dimensions and taper angles.

There are a number of manufacturing refinements that can minimize head-neck junction wear and corrosion. Most important is tightening of tolerances to minimize dimensional mismatch, which will minimize fretting and limit the ingress of fluid and thus minimize corrosion. It has been noted that automotive and machine-tool tolerances are up to eightfold higher than the standards for medical tapers.[17] Hardening by nitriding or nitrogen implantation also can improve the strength and wear resistance of the Morse taper.[14]



A B

Fig. 6 **A,** Trunnion from a retrieved femoral stem demonstrates excessive wear. **B,** Corresponding significant damage to the modular head component.

Stems

Many current component designs have incorporated modularity into various design characteristics of the stem. There are designs that feature modularity between the stem and a collar, a distal sleeve, a metaphyseal segment, and / or proximal pads.

Modularity with the collar represents an attempt to reduce inventory. Relatively few stems offer this option. The extent to which modular collars effectively transfer load has not been established. At least one retrieved prosthesis has shown significant fretting of a modular collar.[7]

The rationale for stem modularity is to achieve better fit and fill, greater initial stability, and more uniform stress distribution while minimizing stress shielding, bone loss, and incidence of thigh pain. Proponents of stem modularity believe that the modular components offer optimal proximal metaphyseal fill and proximal stress transfer with distal fit for initial torsional stability. Modularity potentially provides an adequate number of proximal and distal geometry combinations to facilitate the achievement of maximal direct bone contact with porous coating proximally and stem contact with endosteal cortex distally.

The goal of distal modularity is to obtain distal fit and centering of the stem while reducing stem stiffness. There is some evidence that distal filling and centralization improve the stability of uncemented components.[18] There is also clinical evidence that cementless stems with high degrees of flexural rigidity relative to the surrounding femur are associated with a higher incidence of thigh pain.[19]

An additional advantage of modular stem design is the ability to address unusual femoral geometries. This is particularly beneficial in cases of excessive femoral anteversion, as is often seen in the chronically dislocated hip of a patient with congenital dysplasia of the hip or in revision situations in which the stem has subsided into retroversion. Although modular components offer distinct advantages in these revision and complex primary cases, the other potential advantages remain largely theoretical.

Although photoelastic models have predicted more uniform stress distribution with proximal modular stems, plain radiographs and dual-energy x-ray absorptiometry scans have shown a high degree of proximal bone loss and stress shielding with designs such as that of the S-ROM system (Joint Medical Products, Stamford, Conn).[20] Although better proximal fill may be obtained, greater stiffness of the larger proximal metaphyseal component may lead to significant stress shielding. In addition, a number of investigators have demonstrated a lack of correlation between radiographic fit and fill and clinical results, specifically, a reduction in the incidence of thigh pain.

As with other modular connections, the potential for failure of the modular connection and generation of wear debris remains a concern. Cook et al[21] tested the S-ROM system under axial load in a saline environment and found that slippage can occur under physiologic loads. They found that this situation is more likely if the interface is contaminated. At 8 million cycles, over 8×10^7 particles in the 1- to 2-μm range were generated. Bobyn et al[8] performed similar tests on the S-ROM system, the Infinity system (Wright Medical, Arlington, Tenn), and the Richards Modular Hip System (Smith & Nephew Richards, Memphis) and found somewhat different results. All the modular interfaces were grossly stable, but minor degrees of fretting and surface damage did occur. Although fewer particles were demonstrated (approximately 2×10^7), the number of particles was highly dependent on the method of measurement and varied significantly from one specimen to another. In another study of the S-ROM system,[22] minor degrees of surface damage and fretting were seen. Improvement in the surface finish was recommended to minimize fretting. As with head-neck tapers, tight specifications and surface finish are important factors. Clinical results with proximally modular stems have generally been good. Dissociation has not been reported and lysis has rarely been observed, although it remains a concern (Fig. 7).

Distal modularity has been associated with erosion of the shaft and migration of the distally modular component in some cases (Fig. 8). This raises the concern of wear debris and lysis originating at this interface.

Although stem modularity offers an advantage in complex primary and certain revision situations as an alternative to a custom uncemented stem, the advantage remains theoretical in most primary cases.

Total Knee Replacement

Tibial Inserts

Modular tibial components offer a variety of options for the orthopaedist. The baseplate can be implanted separately, and trial reduction can be performed with modular trial inserts. The tourniquet can then be deflated and the insert can be removed to facilitate control of bleeding in the posterior aspect of the knee and removal of excess

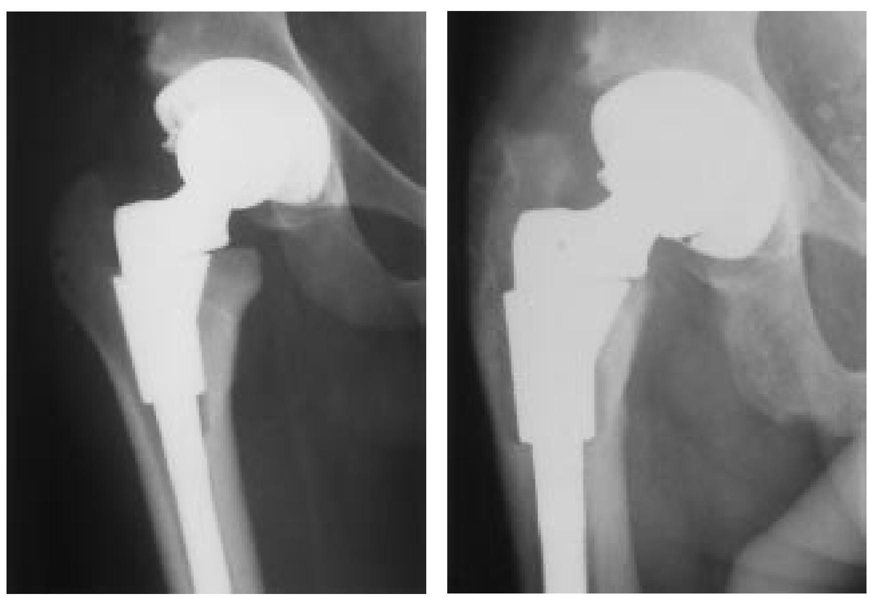


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Fig. 7 **A,** Radiographic appearance of proximally modular stem immediately after surgery. **B,** Five years later, lysis is seen around the metaphyseal sleeve.

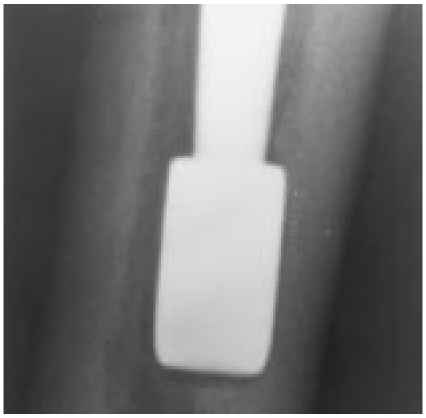

Fig. 8 Erosion of distal bullet of distally modular stem into cortical bone.

cement prior to final insertion of the modular insert. Modular inserts provide a number of choices of thickness as well as degree of constraint of the articular surface. This gives one the option of switching from a posterior cruciate ligament (PCL)-retaining insert to a PCL-sacrificing insert utilizing the same tibial baseplate.

Occasionally a revision procedure is undertaken for excessive polyethylene wear or knee instability. Use of a modular insert makes it possible to simply change to a thicker and/or more constrained liner without disrupting the component-bone interface. Modular tibial baseplates also allow adjunctive fixation by the use of screws through the baseplate, which has been found to substantially add to stability and decrease micromotion in uncemented tibial components, particularly in patients whose bone quality is poor.

Unfortunately, modular tibial components are associated with significant disadvantages. In a number of early designs, the thickness of the polyethylene was less than 5 mm.[23] Modular inserts also introduce the possibility of failure of the locking mechanism used to hold the polyethylene component in place. At least one modular knee design has been recalled because of a series of failures of the locking pin.

With modular inserts there is also the possibility of wear at the interface between the polyethylene and the metal baseplate. A membrane invariably forms at this interface, and concern has been expressed about the possibility that this increases the potential for late infection. To date, there is no evidence to support this concern.[24] Modular tibial components can also increase the likelihood of generation of particulate debris and associated osteolysis. Peters et al[25] reported a 16% incidence of osteolysis in an uncemented modular tibial component. Contributing factors were thought to be failure of thin polyethylene modular inserts, abrasion of the tibial spine with secondary wear, impingement of the locking pin against the femoral component, and corrosion between the titanium screws and the cobalt-chrome baseplate. All of these factors are a direct result of the modularity of the tibial component.

Augmentation Devices

The use of metal augmentation devices to replace deficient bone has been another impetus to increase the modularity of total-knee-replacement components. Utilization of these devices is generally faster and technically easier than replacing the defects with autograft or allograft bone. Metal augmentation is more appropriate for small and medium-size defects than for large defects. Metal wedges or blocks can be cemented to the components, fixed with screws, or snap-fitted. There is some evidence that the block configuration distributes the load more evenly than does wedge augmentation.[26] The major disadvantage is the potential for fretting or failure of the interface, although these events have not been reported. Because of this potential disadvantage, current systems are split between providing modular tibial components that require assembly and providing a large inventory of one-piece integral components with wedge or block augments incorporated into the tibial baseplate.

Stems

Modular stems add additional fixation, which is often necessary because of bone loss in revision knee replacement. A press fit can be obtained in the femoral and tibial canals by utilizing a wide array of lengths, diameters, and both straight and curved options. This allows for a hybrid type of fixation with cementing of the surfaces and press-fitting of the stems. These design features have the added advantage of providing reliable reproduction of the mechanical axis, which is difficult in many revision cases. The press-fit stems are easier to revise should this become necessary, since cement does not have to be placed into the medullary canal of the tibia or femur. At least one clinical review has reported improved results with press-fitting of stems and cementing of only the surface of the tibia and femur.

Disadvantages include increased potential for fracture of the tibial or femoral shaft in an attempt to achieve a press fit with large stems. The large, stiff stems also may cause stress shielding of the distal femur and proximal tibia. In addition, there is the ubiquitous concern of generation of particulate debris from the modular connection or failure of the connection. Press-fitting of the stem also has the disadvantage of dictating the placement of the condylar surface of the femoral or tibial components and the kinematics of the prosthesis. This places additional responsibility on the manufacturer to ensure that the stem is in the appropriate location on the component. In some femoral components, for instance, there is a concern that the stem is posterior to the femoral component, which places the anterior femoral flange anterior to the shaft of the femur. This changes knee kinematics, increases the patellofemoral force with flexion, and effectively produces collateral ligament laxity and potential instability with flexion.

Shoulder Arthroplasty

In recent years there been increasing interest in humeral component modularity. Modular heads offer a wide variety of diameters and sizes. The humeral body can be implanted and final tissue tension can be adjusted with a variety of different head sizes. Probably the single greatest advantage of modular humeral components is the ability to revise or insert a glenoid component without removing the humeral component.[27] Hemiarthroplasty is often performed in young patients for avascular necrosis or posttraumatic arthritis. Modular components allow implantation of a glenoid component at a later date without the necessity of revising the humeral component.

As with modular hip and knee components, the potential for generation of wear debris is a concern. Lysis has not been reported to date; however, experience with these modular components is of very short duration.

The other major concern is component dissociation. There have been a few reported cases of humeral head dissociation with early designs.[28] Dissociation of a modular glenoid has also been reported.[29] The higher shear forces on modular shoulder implants was cited in both reports. Review of complications reported to the Food and Drug Administration between 1986 and July 1993 reveals that 27 of 55 cases (49%) involving shoulder implants were the result of dissociation of a modular component. There were 12 humeral head dissociations and 15 glenoid liner dissociations

Currently, two basic types of taper are available. The main difference is whether the humeral component contains a male or female taper. There is some basis for believing that the male-taper femoral component may provide a stronger locking mechanism, which would theoretically be less likely to dissociate. However, a male-taper component neutralizes the advantage of being able to revise or implant a glenoid

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