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Design Considerations for Cementless Total Hip Arthroplasty

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I. INTRODUCTION

“Technique, technique, technique” is a quote from David Hungerford, M.D. Technique is more important than design or material. In order for a surgical procedure to be considered a success, it must provide reproducible, satisfactory clinical results, reproducibility being the key word. The best implant put in poorly is not as good as the worst implant put in well.

Many varieties of designs for cementless total hip replacement are currently available and provide good to excellent results in the hands of their developers (Fig. 1). However, the challenge comes when these individual designs and techniques expand into the general marketplace. Too often general orthopedists do not appreciate the required technique for a given design. In addition, they often have less experience, and tend to overextend indications. Certainly clinical results have been less satisfactory in the young, active patient population [16,15,29].

There is no question that bone cement has made and continues to make a significant contribution to the success of total hip replacements. However, it is important to recognize its inherent biological and mechanical limitations (low modulus, low fatigue strength, potential toxicity, and propensity for late hematogenous infection). At this time, there continues to be a significant controversy about cement versus cementless fixation. This chapter reviews only cementless considerations.

This review covers anatomy, materials, testing, history, surgical technique, and a look into the immediate future for cementless total hip implants. It is our hope that this text will offer guidelines to students, residents, implant developers, and surgeons, as well as the orthopedic hip specialist.



Figure 1 Varieties of cementless stems.

II. ACETABULAR CONSIDERATION

The hip joint is not a perfect ball-and-socket joint; the femoral head is oval in shape and the articular surface of the acetabulum is horseshoe shaped. The dome of the acetabulum, which has been considered a weight-bearing area, is in fact flexible (Fig. 2). The horns of the acetabulum can thus close up and contact the femoral head when the joint is loaded



Figure 2 Radiolucent triangle.

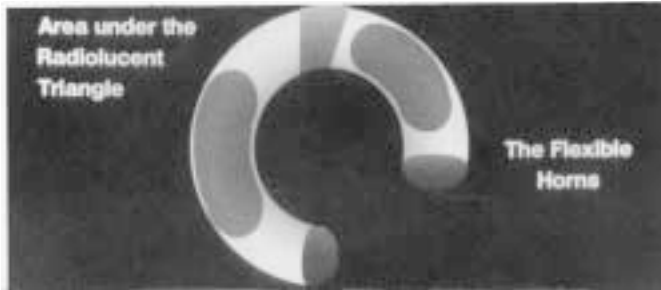


Figure 3 Principal weight bearing areas of the acetabulum.

[33,70]. The degree of this movement is dependent upon age, load, and femoral anteversion. This mobility of the acetabular horns could explain biomechanically the development of aseptic loosening that occurs around acetabular components.

Pauwels describes a radiolucent triangular space above the dome of the acetabulum. [59] (Fig. 3). The shape of this triangle is subject to modifications that are dependent upon femoral loading orientation. In advanced osteoarthritis of the hip the surface area of this triangle decreases and vanishes. It is interesting to note that with age, the hip becomes more congruent and the radiolucent triangle disappears while a trabecular pattern becomes apparent.

Apart from the initial stability at the acetabular implant bone interface, some time after initial implantation is needed for the acetabular horns to become mobile again. This corresponds to radiographic evidence of radiolucent lines in zones I and 3 [8,27] (Fig. 4). In fact, clinical analysis of cemented devices demonstrates considerable progression of acetabular component loosening beyond the 12th year and even earlier in young, active patients [2,17,15,20,26]. This mobility might further explain finding little or no bone ingrowth on retrieved cementless implants [19,61,21,22,23]. Mobility of the acetabular horns must be considered in design parameters if long-term fixation is to be

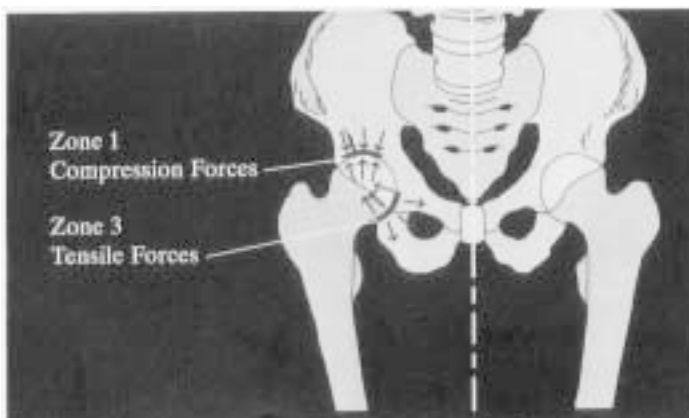


Figure 4 Compressive and tensile forces acting on acetabular components.

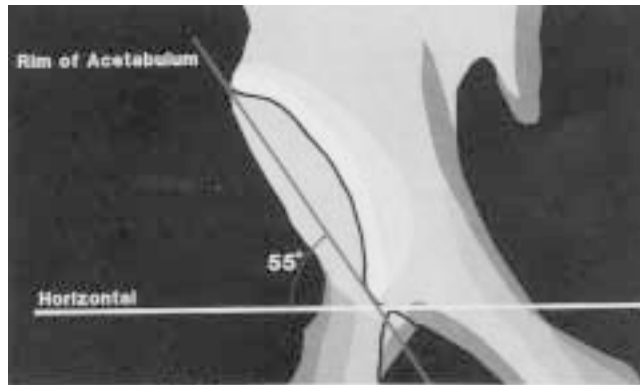


Figure 5 Orientation of acetabulum.

achieved. Fixation is enhanced if the prosthesis is set in a position of less than 45° abduction to promote compression and eliminate tension at the interfaces.

The acetabulum is generally spherical in shape (Fig. 5) and its opening is oriented closer to 55° than 45°, downward in the coronal and sagittal plane, and anteverted approximately 15° to 20° in the midsagittal plane.

Initial acetabular component stability is affected by the cup's ability to engage with the host bone. This is a function of cup design, size, and surgical technique. Cups of a true hemispherical design are more stable than low-profile designs [1]. Adjunct screw fixation can enhance initial stability but may contribute to osteolysis in the long term. Care should be taken to not penetrate intrapelvic structures by screws or drill bits. A study by Perona et al. demonstrated that the ilium provides the least amount of intrinsic support to cup fixation, while the anterior and posterior columns provide more stability [60]. Current technique attempts to press fit 1-2 min of a hemispherical design and only use adjunct screw fixation when necessary. If a modular design is used with dome screw fixation, the anterior superior quadrant of the acetabulum should be avoided because it is the highest-risk area due to the medial intrapelvic vascular structures [73,401 (Fig. 6). When possible, peripheral screws should be used over dome screws due to their greater ability to restrict micromotion of the anterior and posterior columns in addition to being placed in a more appropriate safe zone away from intrapelvic vascular structures.

A. Acetabular Components

Cementless acetabular components are gaining popularity in the United States and in the rest of the world. These implants are indicated for both primary and revision surgery. It appears the bony matrix of the acetabulum is well suited for cementless fixation. Cementless fixation is best accomplished in the well-formed acetabulum where the shape is hemispheric and the implant can be placed in close apposition with the trabecular bone.

Historically, Phillippe Wiles is credited with implanting the first total hip replacement in 1938 [74]. The surgery was performed in London, England, and the implant consisted of two steel components. It was McKee, however, who began to popularize this procedure, beginning his development work in 1940 [49,50]. By 1951 only a limited clinical experience existed. His design consisted of a metal acetabular component that was se-

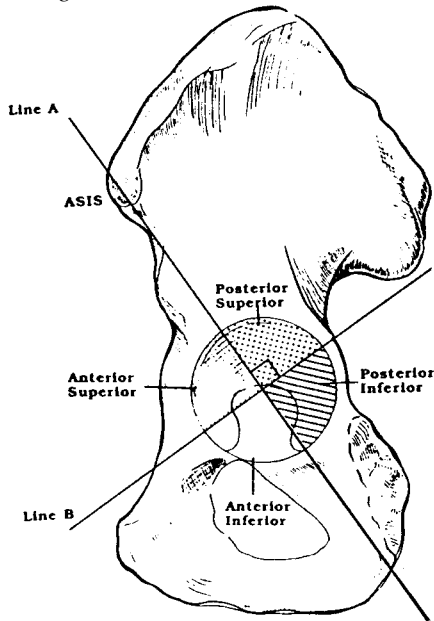


Figure 6 Acetabulum quadrants.

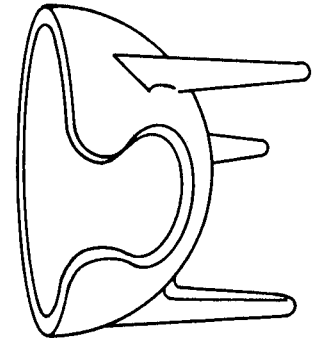


Figure 7 Urist cup.

cured by screw fixation. During this time, McKee helped to identify one of the key problems in total joint fixation, namely, the distribution of forces at the interface between prosthesis and bone.

In 1957 Urist [72] evolved an acetabular cup endoprosthesis similar to the earlier Smith-Peterson cup (Fig. 7). His clinical results, however, were not encouraging since most patients required revision after 2-3 years.

In 1956 Sivash [38], of the Soviet Union, began work on an all-metal total hip design. By 1957 his acetabular model provided a helical thread on its outer surface with a 7 turn pitch and a 110 mm depth. This design proved to be difficult to insert and evolved into a 1962 modification. The 1962 design included four rows of circumferential blades (Fig. 8). Surgical technique required reaming the acetabular rim 3 mm smaller than the diameter of the prosthesis, which allowed the sharp edges to be impacted and rotated into the bony rim. Additional fixation was achieved by the use of screws placed through the rim of the prosthesis [68].

In 1969 Boutin, of France, introduced the use of porous ceramics as a means of attachment [10,11]. At about the same time, the Judet brothers began an acetabular design that achieved fixation through a series of bone screws but rapidly failed because of the acrylic head [39].

These developments created the initial interest in the search to find a satisfactory and enduring method of skeletal attachment for acetabular components. However, the introduction of acrylic bone cement for fixation by Chamley soon led to its widespread use and the abandonment of attempts to develop cementless designs [18]. As clinical reports of long-term cemented hip replacements began to emerge, concerns were raised about the mechanical longevity and the osteolytic potential of fragmented bone cement [75,36]. In an attempt to overcome some of these problems, Harris began a clinical series in the early 1970s utilizing a metal-backed component to be used with acrylic bone cement (Fig. 9). The metal-backed design sought to reduce peak stresses at the bone-cement

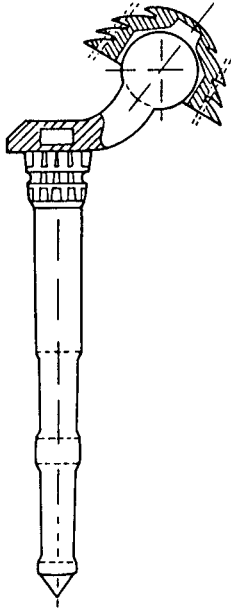


Figure 8 Sivash 1962 design.

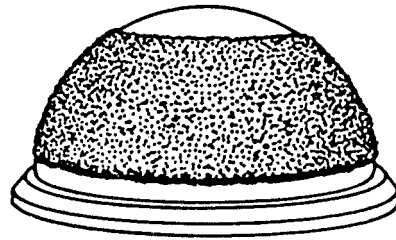


Figure 9 Harris cup.

interface, to contain and support the poly insert, and to reduce cold flow with the option of insert replacement due to wear [34].

In 1982 Noiles introduced the S-ROM™ threaded design that was evolved from the earlier Sivash design (Fig. 10). The design featured a low-profile, self-cutting cup that was inserted through impaction and torque. This was the first acetabular component that offered optional angled poly inserts to enhance joint stability.

Mallory, McTighe, and Noiles [51] further collaborated on the S-ROM by adding regionally placed porous coatings (Fig. 11). This design, called the Super Cup-, offers immediate mechanical skeletal fixation by the feature of threads and also allows for the potential of long-term bone ingrowth into the porous beads. This design continues to be used in the United States.

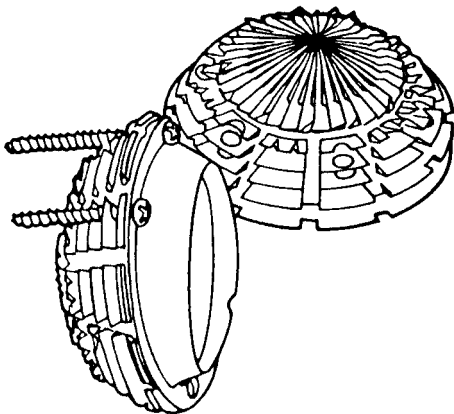


Figure 10 1982 S-ROM design.

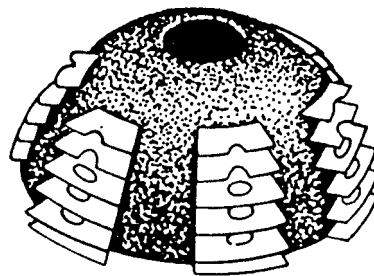


Figure 11 Super Cup design.



Figure 12 Mittelmeier ceramic cup and press fit stem.

Threaded acetabular components, as compared to porous press-fit designs, have had the longer history of cementless application in total hip arthroplasty. The Europeans have pioneered and championed this concept in both primary and revision surgery.

Lord [46] and Mittelmeier [56,57,58] have both reported comparable results, with approximately 90% good to excellent results for primaries and 75% good to excellent results for revisions. Mittelmeier continues to use his ceramic threaded device today (Fig. 12). The success of the Europeans spurred enthusiasm in usage in the United States and by 1986 threaded designs were being promoted by most implant companies.

Bierbaum, Capello, Engh, Mallory, Miller, and Murray are a few of the pioneers of clinical usage of threaded devices in the United States [5 11]. Each has encountered different degrees of success with various designs. As of this writing, none of these surgeons are currently using threaded devices for primary or revision surgery.

The lack of a full understanding of the design features and the required surgical technique, along with proper indications and contraindications, predisposed some of these devices to failure. First and foremost in the successful implantation of a cementless device, and particularly a threaded device, are exposure and surgical technique. Acetabular exposure must be greater for these devices than for conventional cemented cups. Threaded components have a major, or outside, diameter larger than that of the prepared dimensions of the acetabulum. It is therefore necessary to directly face the acetabulum for insertion of these threaded devices.

There are four basic classifications of threaded cup designs. It is crucial to understand the differences in these designs and most of all to understand the particular design chosen for implantation. A complete understanding of the design will enable the surgeon to maximize surgical techniques to achieve a good result.

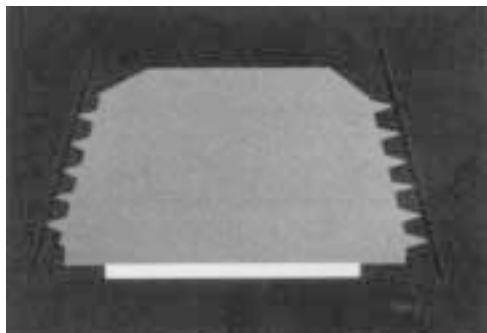


Figure 13 Truncated cone.

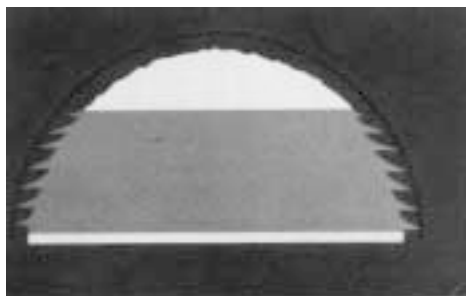


Figure 14 Hemispherical ring.

B. Threaded Cups

Classification of Threaded Cups

This section discusses four classifications of threaded cups:

- Truncated cone (Fig. 13)
- Hemispherical ring (Fig. 14)
- Hemispherical shell with conical threads (Fig. 15)
- Hemispherical shell with spherical threads (Fig. 16)



Figure 15 Hemispherical shell with conical threads.

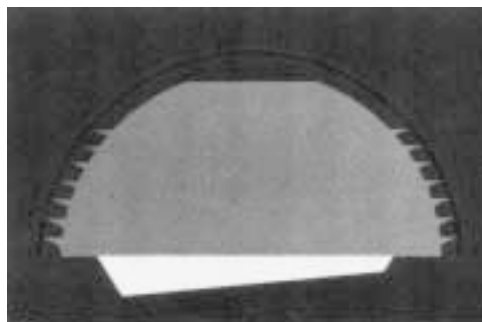


Figure 16 Hemispherical shell with spherical threads.

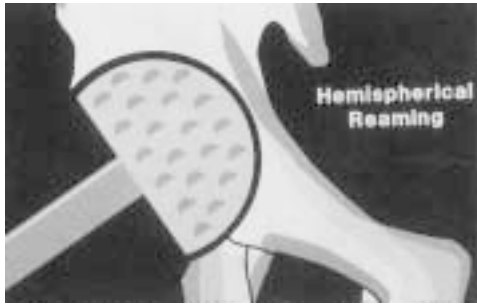


Figure 17 Hemispherical reaming.

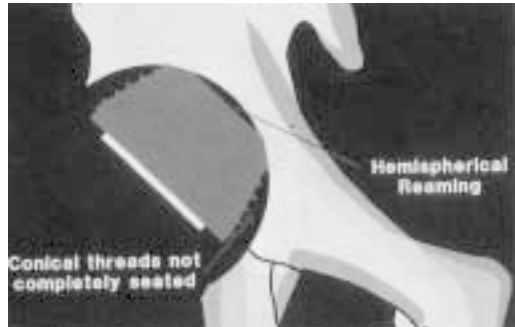


Figure 18 Hemispherical reaming with truncated cup.

1. Truncated Cone

The truncated cone is the design of most European systems, including both Lord and Mittelmeier devices. Whether the truncated cone design is a cup or a ring, the geometry of a truncated cone makes the design inherently very stable. However, it does require more bone removal than a hemispherical design (Fig. 17).

Although very successful in Europe, these designs have not met with great acceptance in North America. The surgical technique required to ensure proper seating for a truncated cone is quite demanding. If reamed spherically, the threads engage very little bone (Fig. 18). If deepened with the reamer, contact between implant and bone is increased. However, bone stock is sacrificed. It appears the device must penetrate subchondral bone in the medial wall to ensure maximum purchase (Fig. 19).

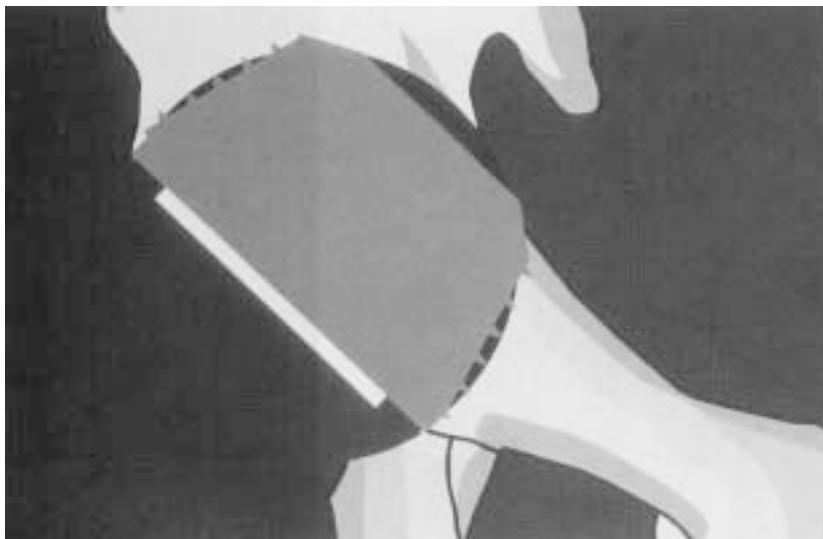


Figure 19 Proper position for truncated cone cup.



Figure 20 Thread profiles.

2. Hemispherical Ring

The Mec-ring” from Germany appears to be the most popular ring design. It is a threaded ring, spherical in shape, with a large apical hole. This apical hole allows the poly insert to protrude through the ring, thus interfacing with the prepared acetabular bony bed.

A close look at this design raises some questions and concerns. The thread buttress angle provides for maximum pull-out resistance. However, this is not the mode of loading for threaded cups. Since the majority of the loads placed on the acetabular component are in compression, a horizontal thread profile would be more appropriate for proper load transfer (Fig. 20). An extremely large apical hole allows for more load transfer to the thin fossa as compared to designs that have either a small hole or an enclosed dome (Fig. 21).

The designs with a smaller hole do not allow the poly inserts to protrude through the hole. These are classified as cups, not rings.

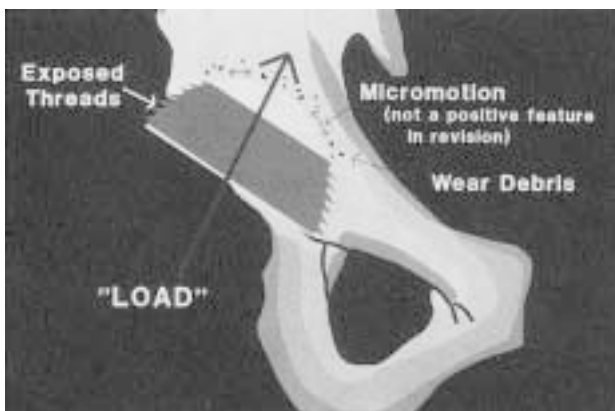


Figure 21 Threaded ring.

In revision situations where the subchondral bone is diminished or lost, loading should be transferred to the periphery to protect or shield this area.

Earlier designs had only neutral-angle poly inserts requiring a more horizontal orientation of the cup to ensure joint stability. This type of positioning can compromise bony coverage of the implant, resulting in less implant fixation. In addition, if any micromotion occurs between poly insert and bone, the possibility of wear debris exists [71,43].

3. Hemispherical Shell with Conical Threads

This is the design of most U.S. manufacturers. The hemispherical shell has an advantage over a truncated cone because it allows preservation of the subchondral bone by reaming hemispherically. The conical threads are much easier to design and manufacture as compared to spherical threads. However, the conical thread does compromise maximum potential for seating the entire thread into a hemispherically reamed acetabulum.

4. Hemispherical Shell with Spherical Threads

The S-ROM Anderson TM Cup was the first hemispherically domed shell with spherical threads. Note that the thread buttress angle provides maximum resistance to the compression loads going into the acetabulum. The apical hole is small enough to reduce

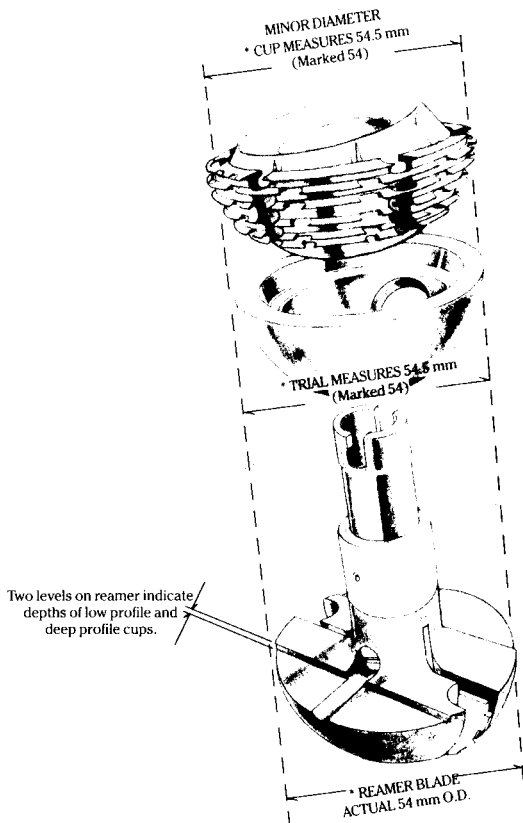


Figure 22 Reamer versus threaded cup diameter.

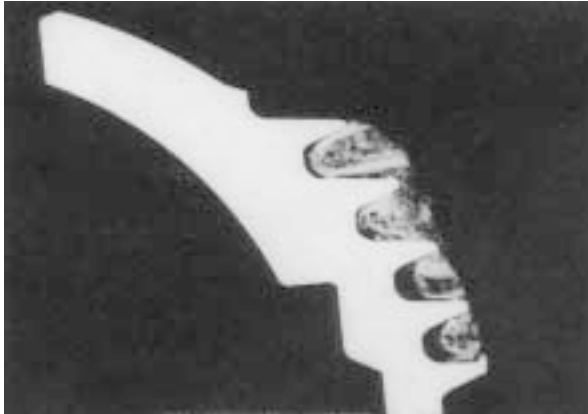


Figure 23 Cross section of retrieved threaded cup.

loads that are transferred through the apex; however, the hole is still large enough for visualization and access for bone graft material.

The major diameter of the thread is 5 mm greater than the diameter of the trial. Therefore, the penetration of each thread is 2.5 mm relative to the dome and flute spherical surface. The actual thread minor diameter, or root diameter, is such that the root of each thread lies 0.5 mm below the dome and cutting flute's spherical surface, thus allowing 0.5 mm space for bone chips from thread cutting to accumulate (Fig. 22).

By 1990 most threaded devices, with the exception of the S-ROM Super Cup, had been discontinued from routine use in both primary and revision surgery (Fig. 23).

It is important to note that threaded acetabular components are not all the same, just as porous and cemented designs are not all the same. Only full understanding of the chosen design and the required technique for that design will ensure a good, long-lasting result.



Figure 24 Porous cups.

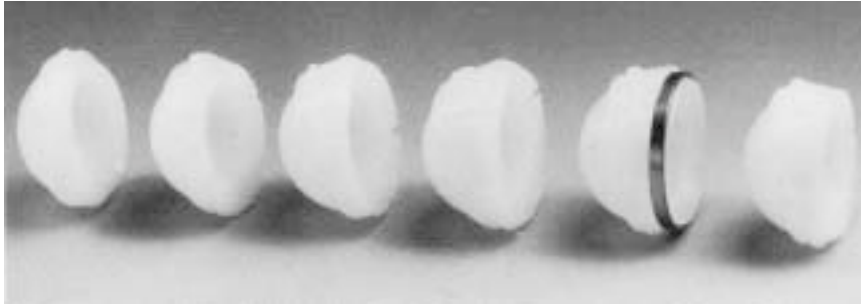


Figure 25 Polyethylene lines available in different angles.

C. Modular Acetabular Components

Two-piece, modular porous acetabular components have gained major market acceptance in total hip arthroplasty (Fig. 24). The main advantage over threaded devices is ease of insertion. Adjunct fixation can be enhanced by bone screw fixation. Polyethylene liners come in a variety of head diameters as well as offering different offset angles to enhance head coverage (Fig. 25). However, as pointed out by Krushell et al., elevated polyethylene liners are not without problems [42]. Elevated rim liners increase range of motion in some directions and decrease range of motion in other directions. They do not in any global sense provide greater range of motion than a neutral liner. Therefore, routine use of an elevated rim liner is not recommended. If a cup is malpositioned, a liner might offer some immediate implant stability; however, polyethylene is not a good material for structural support, and cold flow, deformation, disassociation, and late joint dislocation are real probabilities. It is preferable to reposition the metal cup rather than relying on polyethylene to function under high loads.

However, these modular designs are not without problems. Since their introduction, osteolysis due to particulate debris has increased in cementless total hip arthroplasty.

The most common cause of proximal, femoral bone loss is due to osteolysis [52,9] (Fig. 26). Although the specific cause of lysis is not known, it has been attributed to a variety of factors such as motion of the implant. Foreign-body reaction to particulate debris, in particular to polymeric debris, probably plays the greatest role. It has been almost two decades since Willert et al. first described the problem of polyethylene wear

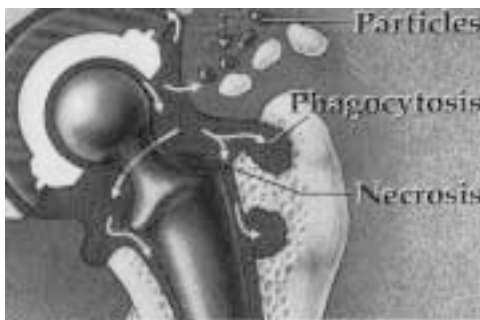


Figure 26 Osteolysis.



Figure 27 Bone loss due to particulate debris generated osteolysis.

leading to periprosthetic inflammation, granuloma, bone resorption, and implant loosening [75]. Since then, many studies have documented the finding of particulate bone cement and polyethylene in periprosthetic tissue [36,661].

In normal-wearing artificial joints, linear wear rates of 0.05-0.2 mm per year result in the generation of about 25-100 mm (25-100 mg) of polyethylene debris annually. On a basis of known dimensions of polyethylene particles found in tissue around the hip prosthesis, this equates to the annual production of tens to hundreds of billions of particles [9].

Variations of polyethylene wear rates probably relate to acetabular implant design, femoral head size, femoral head material, and at least in part to the quality of the polyethylene used [44,2]. Wide variations are known to exist between batches of polyethylene and between different polyethylene suppliers [761].

Metal particulate debris generated from the stem or cup in sufficient quantities could activate macrophage-mediated osteolysis. More likely the cause is the migration of metallic debris into the articulation, resulting in increased third-body wear of polyethylene (Fig. 27). Additional poly debris can be generated by poor modular designs, incomplete conformity of the liner within the metal cup, thin polyethylene resulting in cold flow, and wear through and abrasion of screw heads against the convex polyethylene surface (Fig. 28).

Problems with excessive wear due to titanium bearing surfaces have been reported (Fig. 29). In addition, clinical evidence indicates higher volumetric wear with 32 mm heads.



Figure 28 Incomplete conformity of cup and poly insert.

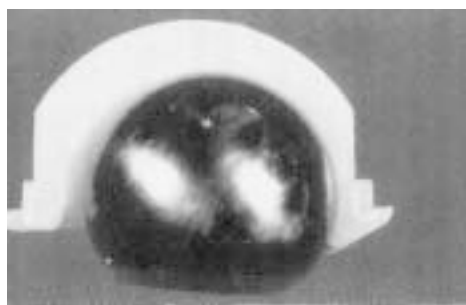


Figure 29 Excess wear due to titanium head.

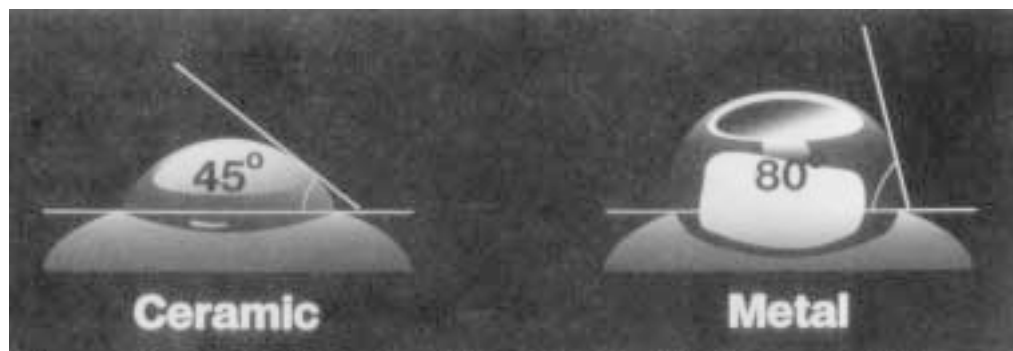


Figure 30 Wettability of ceramic versus metal.

Ideally, the bearing surface for most sliding (Fig. 30), rotating, or articulating bearing surfaces will be made from material having relatively high strength, high wear, and corrosion resistance; a high resistance to creep; and low frictional movements. In reality no one material presently exhibits all of these characteristics. Therefore, with present bearing systems compromises are typically made between these various characteristics. There are, however, some immediate steps that can be taken to reduce the generation of particulate debris.

1. Use ultra-high molecular weight polyethylene with high ratings in key mechanical and physical properties.
2. Use non-modular, molded acetabular components.
3. Use modular components with:
 - High conformity and support.
 - Secure locking mechanism.
 - Minimum polyethylene thickness 6-8 mm.
4. Use a 28 mm or smaller head diameter.
5. Do not use titanium alloy as a bearing surface.
6. Minimize modular sites on femoral side to reduce chances of third-particle wear debris.

III. FEMORAL CONSIDERATION

The femoral head is slightly larger than one half of a sphere, and the shape is more oval than spherical. The stresses on the femoral head usually act on the anterior superior quadrant, and surface motion can be considered as sliding on the acetabulum. Two important angles need to be considered: the neck shaft angle and the angle of anteversion. In addition to these two angles, the joint reaction force is affected by femoral head offset [28,65,37]. It is also important to remember that while static force is considerably greater than body weight, even greater force is generated posteriorly in dynamic situations such as acceleration and deceleration: manifest in negotiating stairs or inclines, in changing from a sitting to a standing position or vice versa, and in other routine activities of daily living that load the hip in flexion.

The biological response of bone to stress greatly affects the outcome of cementless total hip arthroplasty. The adaptive bone remodeling process, “Wolff’s law”, must be taken into consideration in deciding on material, geometry, and size selection for cementless femoral components. Many clinical and radiological studies have demonstrated the sensitivity of this adaptive remodeling process [3 11 (Fig. 3 1).

It has been shown that trabecular microfracture and remodeling is a major mode of accelerated remodeling in response to changes in mechanical demands on the bone [321. Trabeculae that fail, either by fatigue mode or by overloading, will disappear if the ends do not contact each other and if the resulting trabecula bears no load (disuse atrophy). However, if the fractured trabecula realigns itself and the fracture site still maintains control such that the structure is able to transmit load, the trabecula will remodel in the new direction much more quickly than through the mechanism of ordered resorption and apposition. Interfaces created surgically within the structure and subsequently loaded by mechanical means result in severe overloading of the remaining cancellous structure.

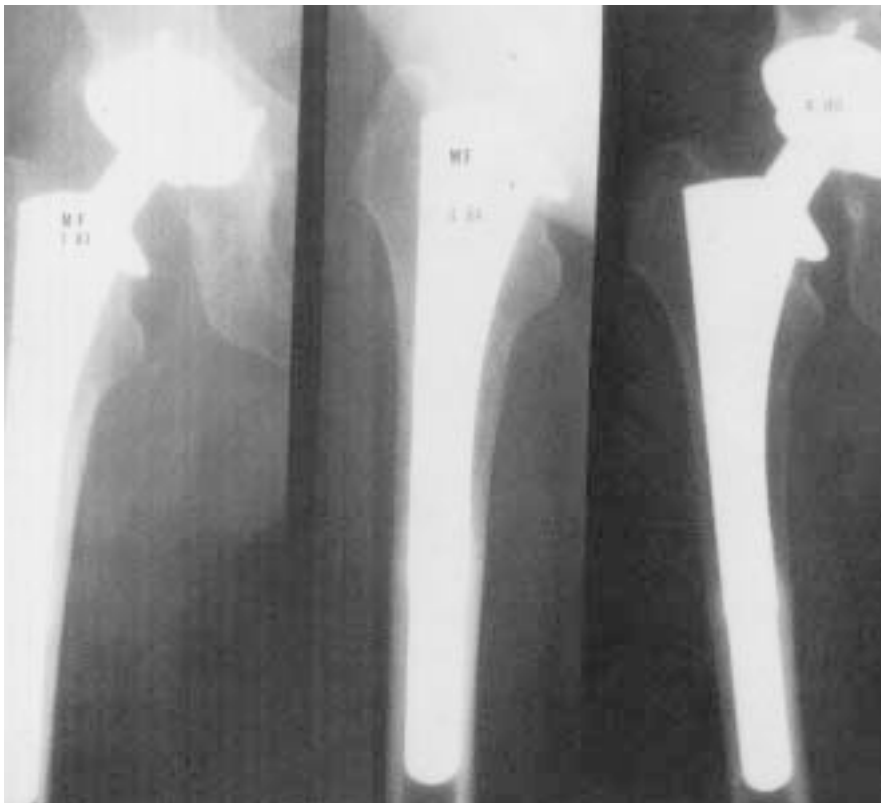


Figure 31 Bone remodeling in a porous coated AMLI stem.

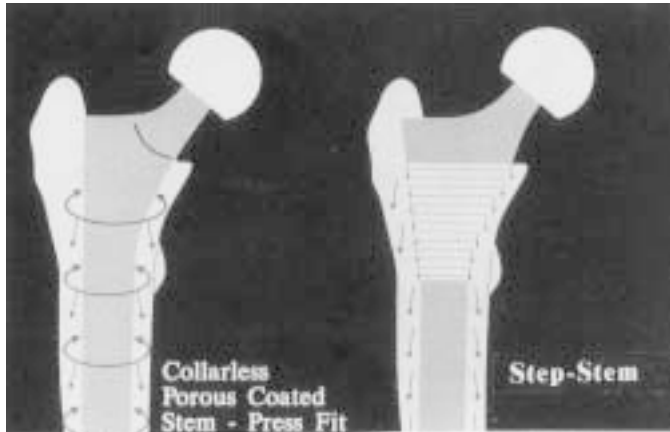


Figure 32 Hoop stresses versus compressive stresses.

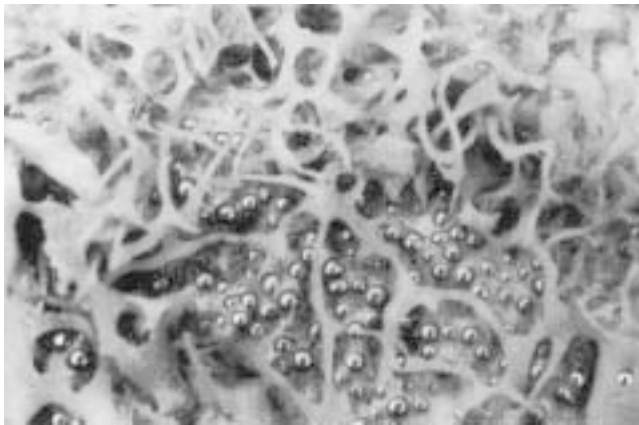


Figure 33 Bone ingrowth into a porous surface.

Cancellous bone is a poor material for structural support of a prosthesis. Cancellous bone is a biological engineered material, and its strength depends on its having the entire bulk of the structure intact. The creation of an interface with areas of cancellous bone disproportionately weakens the structure. In addition, interfacing an implant with cancellous bone merely serves to increase the stress at the interface to a level that causes fatigue failure of the bone [62].

Through proper design and surgical technique, one can achieve significant enhancement of the mechanical properties of the procedure consistent with basic biomechanical principles. It is recommended that most, if not all, of the cancellous bone be removed. Structuring the surface of an implant will minimize the surface shear stresses. In addition, structuring will transfer hoop stresses into compression stresses within the femur (Fig. 32). For an uncemented femoral component to be successful it is universally agreed that initial stability is essential. In addition, there must be a mechanism to ensure longterm bony fixation (Fig. 33).

During the past three decades, techniques, materials, and prosthetic designs for cementless total hip arthroplasty have been improved significantly. During the last 15 years in particular, there has been a growing movement into more complex cementless designs, particularly in the area of modularity. (Fig. 34). Not all cementless designs are equal, and it is important to understand certain design features that segregate individual implants into specific categories within the cementless group. Some appear to be successful whereas others have failed rapidly. To date, all current cementless designs have one feature in common - a modular head. So the simplest of designs features a unibody stem with a modular head that takes either a metal or ceramic articulation (Fig. 35). However, there is a fast-growing trend to add additional modular features to aid in achieving initial implant-to-bone stability by better fit and fill criteria, that is, maximization of endosteal contact.

Replacement of the normal position of the femoral head is essential for correction of mechanical balance between abductor forces. This is addressed by vertical height, version angle, and medial offset of the head relative to the axis of the stem (Fig. 36). If vertical height is too short, joint stability is a problem. If too long, patient complaints result and nerve palsy is possible. Incorrect version angle can result in reduced range of



Figure 34 Multimodular design.

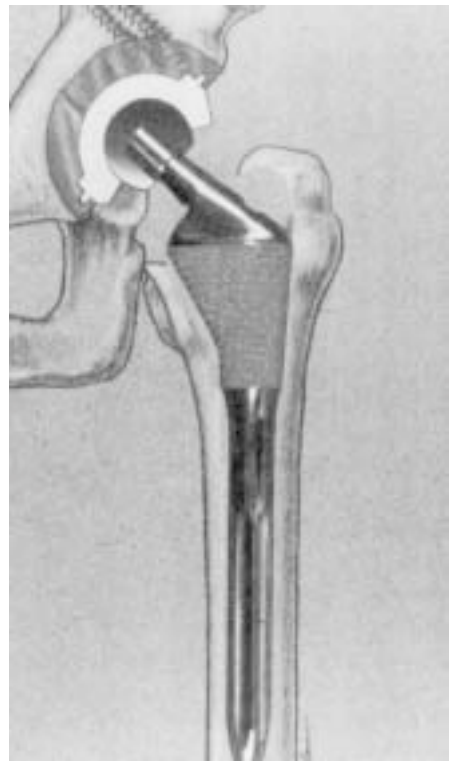


Figure 35 Unibody stem design with modular head.

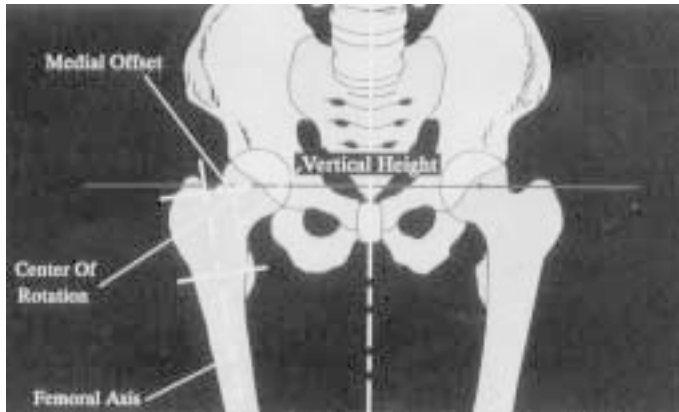


Figure 36 Biomechanical function.

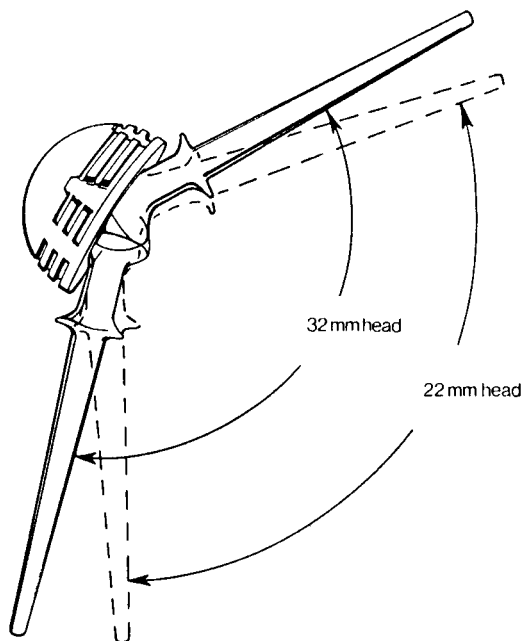


Figure 37 Range of motion.

motion and possible hip dislocations. Medial offset that is too short will cause shortening of the abductor moments, and there will be greater resultant force across the hip joint. If offset is too great, increased torsional forces will be placed on the femoral implant. For a femoral component to be successful it must have initial torsional stability with or without cement.

Modular head diameters are available from 22 to 32 mm. Charnley strongly advocated a 22 mm head due to its lower frictional properties [171]. However, joint stability is not as good as in a larger-diameter head (Fig. 37). Most designers and surgeons now compromise on a 26 or 28 mm diameter, which provides adequate polyethylene thick-

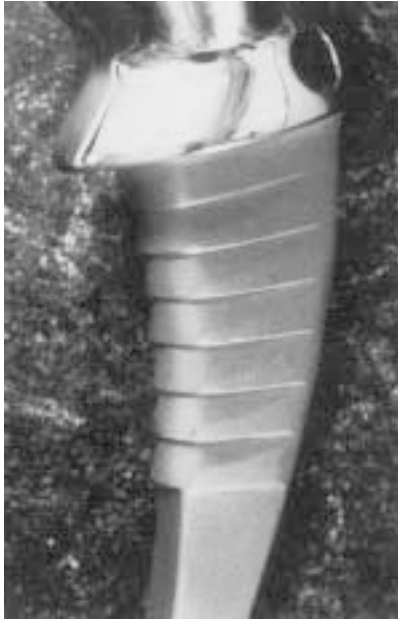


Figure 38 Betchel stepped stem.

ness on the acetabular bearing side, as, well as improved range of motion and stability compared with a 22 mm diameter [44].

Normally the femur is loaded from the outside cortex, and stresses are transferred internally. However, in a stemmed reconstruction the biomechanical loading has been changed to an internal loading mechanism. Intramedullary stems place an unnatural hoop stress on the bone. This hoop stress must be transferred into compressive loads to the

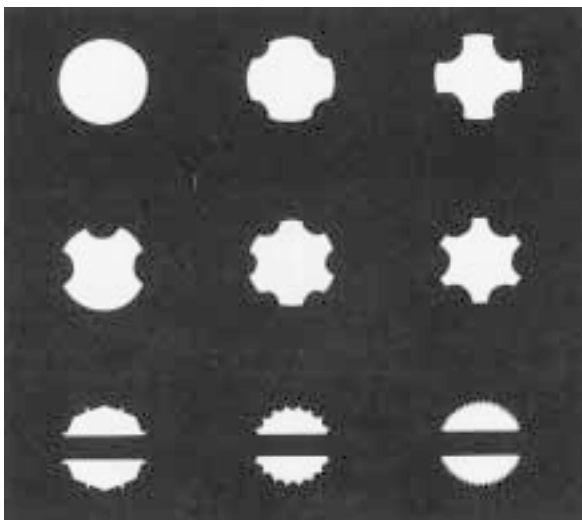


Figure 39 Distal Cross-Sectional Geometry.



Figure 40 Femoral cavitory and segmental defect.

proximal femur. One way to help accomplish this is to design proximal steps into the femoral component. Early endoprosthetic stems were developed by Bechtol in 1954, the “Stepped Prosthesis””, and a later one by Townley also featured this stepped-design concept (Fig. 38). However, the idea was not revisited until Pugh’s work in 1981 led to the OmniFifl design and his additional work that led to the 1984 S-ROM proximal sleeve design [62,63].

A. Femoral Components

The objective for cementless total hip stems of long-term pain-free stability is dependent on both primary and secondary fixation of the implant to the bone. An effective cementless stem should resist subsidence, tilting and torsional forces.

Primary mechanical stability is, therefore, a prerequisite for long-term success. Torsional fixation of the femoral component is considered the most important criteria for long-term success [48]. It is only logical that design features that improve fixation are likely to improve clinical results.

Although there may be advantages in bone remodeling by initial stability by proximal fixation, irregularity in shape and structure of the bone in the metaphyseal area can compromise stability. It has been previously reported that a constant proportional relationship is not present between the shape and size of the metaphysis and diaphysis. In addition the revision situation results in alterations in the normal bony architecture, making fit and fill more difficult to achieve [47,67]. Distal stem stability enhances overall initial stability of the implant in both primary and revision total hip arthroplasty. (Fig. 39).

With cavitory and segmental bone damage it is difficult to achieve stability of the implant (Fig. 40). In this situation some authors have previously recommended distal fixation. It is our opinion that distal stability is preferable over distal fixation. This can be

achieved by fluting the distal end of the stem. Whiteside [48] and Koeneman [45] have shown that fluting offers more initial stability in torsion as compared to a fully porous coated stem.

It is generally agreed that the better the fit and fill ratio of the femoral component, the better the initial stability and potential for long-term fixation. Over the past 10 years fit and fill has taken several approaches: (1) a large quantity of sizes (unibody); (2) modularity; and (3) custom (intraoperative or preoperative).

B. Unibody Stems

Due to concerns that modular sites generate particulate debris along with socioeconomic pressures, there is a strong movement back to one-piece stem designs, especially for routine primary hip reconstruction. The challenge for unibody designs as with all designs is to optimize fit and fill, to ensure optimal loading of stress to the proximal femur, to avoid the problems of torsional and axial instability while providing for reproducible surgical technique.

Currently there is considerable controversy as to straight (Fig. 41) vs. anatomical (Fig. 42) and collar vs. collarless stem designs. In an attempt to appeal to both mentalities, newer geometric designs (Fig. 43) are emerging. These designs feature straight stems with anterior flares and anteverted necks.

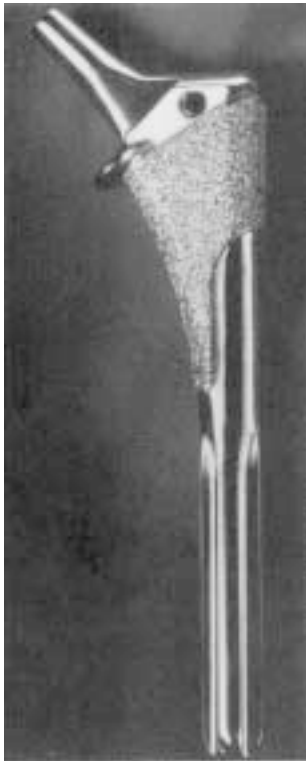


Figure 41 Multilock™ straight stem.

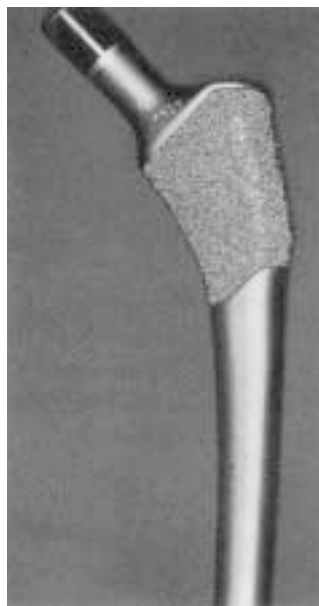


Figure 42 PCA™ Anatomic stem.

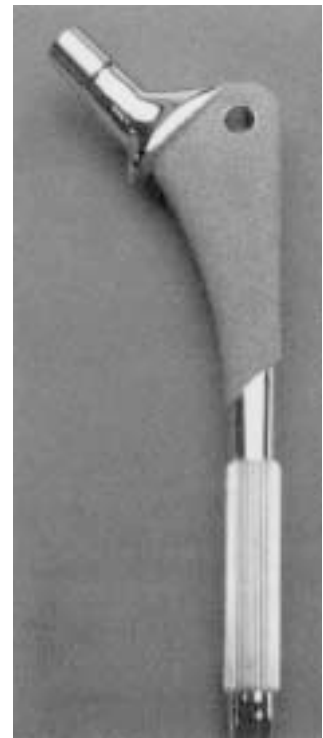


Figure 43 Replica™ geometric stem.

C. Modular Stems

The concept of modularity is to provide for intraoperative customization of fit and fill with each individual femur. There are a variety of modular designs available, from modular necks (Fig. 44), proximal (Fig. 45) and distal sleeves (Fig. 46), and mid-stem tapers (Fig. 47). Each design has specific features and benefits and requires complete knowledge of each individual design and surgical technique.

While modular designs represent an advance in the ability to precisely fit the implant to the bone, the mechanical integrity of the assembled component must be fully tested prior to clinical usage. Machining methods, tolerances, surface characteristics, materials, electrochemical environment and mechanical environment are all critical factors that



Figure 44 Modular neck.



Figure 45 S-ROM stem.



Figure 46 Example modular distal sleeves.

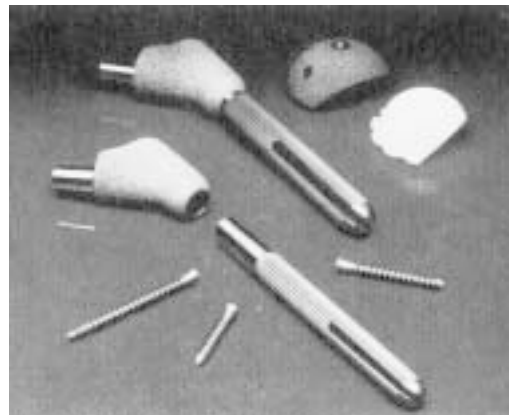


Figure 47 Mid-stem taper design.



Figure 48 Example of increased wear of bearing surface.

need careful consideration in evaluating the long-term performance of modular interfaces [69].

In evaluating the mechanical performance of cementless femoral stems, there is no single test that can adequately represent the various bony conditions that a hip stem may be subjected to *in vivo*. This in part explains the wide variance in testing methods found today.

Recently, concern about particulate debris generated by modular interfaces has been raised. In fact, we are now beginning to see published reports concerning *in-vitro* testing of modular designs [41,24]. One major concern of metal particulate debris, is the possibility of increasing the rate bearing surfaces wear (Fig. 48).

Modularity has been shown to be cost-effective and offers many intraoperative custom capabilities [47,67]. Short-term results are very encouraging and have high appeal

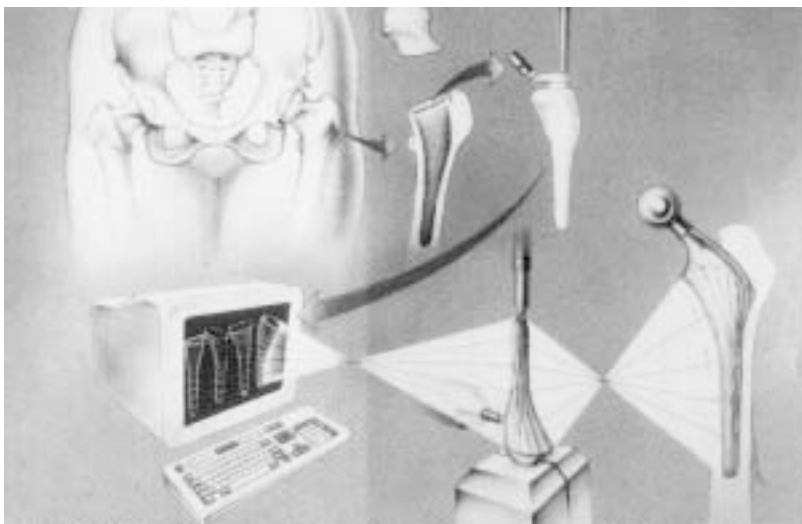


Figure 49 Intraoperative custom.

for revisions and difficult primaries such as congenital dysplasia [14]. However, modularity has made surgical technique more demanding.

D. Custom Stems

Customs offer great versatility; however, intraoperative customs reduce surface treatments such as hydroxyapatite (HA) or porous surfaces (Fig. 49). In addition, there is the concern of increased operating room time and the difficulty in achieving reproducible, clinical and surgical results [30]. As for preoperative customs, again, in routine cases there are no outcome data to support this approach over standard off-the-shelf designs, which generally speaking are less costly. It will take another 10 years of clinical comparison to judge whether customs have an advantage over standard off-the-shelf cementless devices. This is one problem in total joint surgery that does not seem to exist in other medical disciplines. In the meantime, it follows that advances must be made based mainly on theoretical grounds, good solid, basic science, and animal experimentation rather than on short-term clinical evaluations by the implant-developing surgeon in a small number of patients.

Obviously there is a need for all three types of implant modalities: unibody, modular, and customs (although these are not necessary with adequate modularity).

However, the surgeon must be aware of all the design features and pick and choose the appropriate design indicated for individual patients. No one design is going to fill all the needs that are found in total hip replacement surgery today. The future challenge will be to address growing indications in a restricted health care financial market.

IV. MATERIAL CONSIDERATION

Biomedical materials are synthetic polymers, biopolymers, natural macromolecules, metals, ceramics, and inorganics such as hydroxyapatite. For materials to be used successfully in the body, they must have minimal degradation in the body, they must be compatible with the biological environment, and they must be strong enough to perform their intended purpose.

Stainless steel, especially 316L, has been used for many years as an implant material [3,51]. Early total joint replacements and current internal fracture fixation devices utilize stainless steel. In some designs this material has shown crevice corrosion. Cobalt-chrome alloys have been popular as implant materials because of their corrosion resistance and good wear properties. CoCrMo alloy is typically used in devices that are cast.

Forged parts are made from CoNiCrMo alloy. These alloys have relatively high elastic moduli. A desire for a lower modulus material led to the use of titanium and its alloys. Commercially pure titanium is used because of its corrosion resistance, but it is not used in applications that require high structural strength. The titanium alloy that has been most widely used in orthopedic applications is the Ti6Al4V alloy. This material has good fatigue properties but is softer and has lower resistance to wear, especially when extraneous materials are introduced [2,6]. Surface treatments of these alloys have shown improved wear resistance. Titanium alloys with moduli even lower than the Ti6Al4V alloy are beginning to be used. Specialty applications that utilize a change in part shape after implantation use an alloy that is approximately one half nickel and one half titanium, which returns to an original shape under body temperature. These materials are tolerated well by body tissues. Tantalum has excellent biocompatibility and is used for

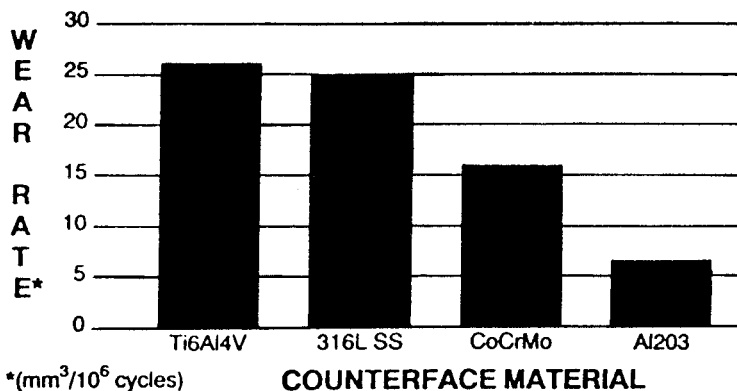


Figure 50 Wear rates.

markers because of its high radiodensity. With all metals there has been a concern for long-term protein-metal interactions and hypersensitivity of individuals to some of the metal ions that diffuse into body tissues.

Aluminum oxide ceramics have been used extensively as bearing surfaces in artificial joints because of its excellent wear properties [25,57,64] (Fig. 50). It has not been used extensively for other structural applications because of its high elastic modulus and brittleness. Zirconia has been introduced recently as an alternative to aluminum oxide.

Polymeric composite materials have been investigated as implant materials. Carbon, glass, quartz, and polymeric fibers have been used for the reinforcing phase, and carbon (carbon-carbon composites), epoxy, polyetheretherketone (PEEK), polybutadiene, and polysulfone have been used as matrices.

Initial testing of artificial implants was prompted by a fatigue fracture rate of about 3 % in early (1970s) femoral stems of artificial hip implants [61] (Fig. 51). The test methods that were developed simulated the failure mode of these early implants. Both the American Society for Testing and Materials (ASTM) and the International Standardiza-



Figure 51 Fractured cemented stem.

tion Organization (ISO) have test methods for femoral stems that support the distal stem and leave the proximal stem unsupported. Although noncemented stems rarely have this type of failure mode, these stems are often tested with this test method. The disadvantage of the method is that if the stem is designed to pass the test, it encourages a bulky and stiff design. This is the opposite of what is needed for maintenance of bone strain and what is desired to combat bone resorption due to stress shielding. An alternative test method that has been reported utilizes proximal fixation with a free distal stem except for a point load on the lateral stem. Both ASTM and ISO are developing test methods to be used with low-stiffness stems. Similar fatigue tests have been developed for other joints such as the knee. Loading typically is at high frequency and at loads higher than expected in service. Ten million cycles has been chosen as representing a run-out; that is, the load is probably below the endurance limit.

V. SOCIAL-ECONOMIC CONSIDERATION

There is no debate on the fact that cost is becoming more and more an influence on the decision process for medical treatments and on product development programs.

A. The Current Health Care Environment

The health care environment includes the following important characteristics:

- Enormous duplication of services Competition among providers
- Technology that changes faster than clinical practice
- Pressure from payers for less costly service
- Pressure on providers to deliver care in a capitated environment
- Vertical Integration and consolidation
- Pressure for information on the value of new approaches

B. Factors Influencing Adoption of New Technology

Several factors are involved in adoption of new technology:

- Method of financing the initial cost
- Method of recovering operating costs Level of regulation
- Degree of competition Institutional capacity for technology assessment
- Organizational relationships: shared risk means slower adoption

C. Implications for Developers

Developers need to consider the following:

- Move from better medicine to better medical economics
- New is not synonymous with improved
- Expect a bumpy ride in an increasingly volatile market
- Focus product development
- “In God We Trust. All others bring data.”

VI. IMMEDIATE FUTURE TRENDS AND PRODUCTS

Use of modularity in the acetabulum has contributed to significant debris generation problems (Fig. 52) [4,9]. This trend is slowly reversing and it is predicted that developers will go back to preassembled, metal-backed, porous-coated devices with molded polyethylene inserts rather than machined. One such ideal design would have the following characteristics:

- Hemispherical shape
- Sintered, porous beads for ingrowth
- Polyethylene, compression molded directly to metal shell
- Peripheral screw holes for adjunct fixation with no dome screw holes and/or a capping mechanism to seal the holes
- Neutral poly liner (no offsets)

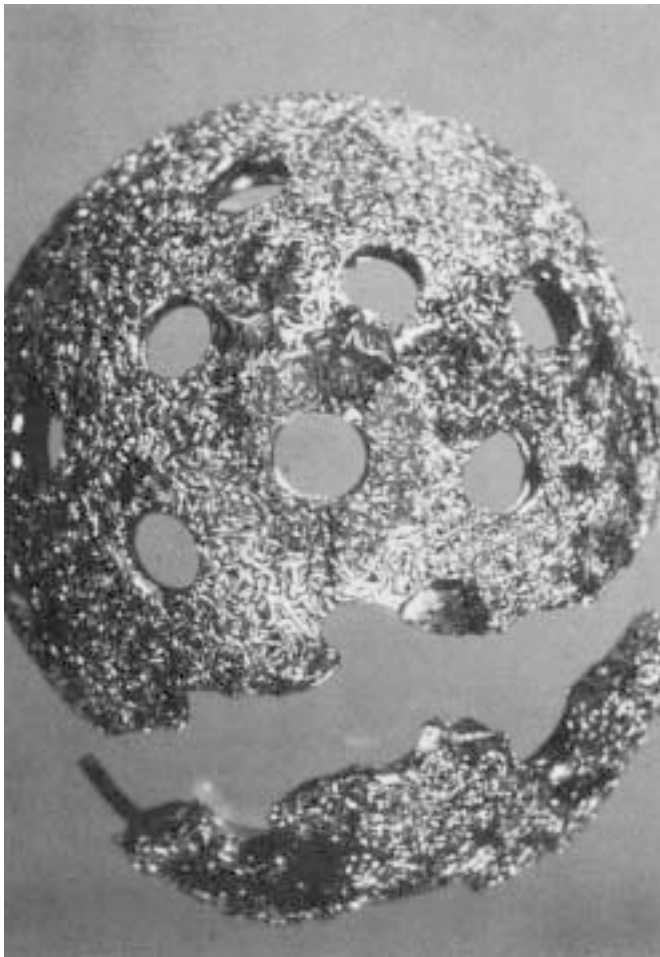


Figure 52 Failed porous mesh cementless cup.

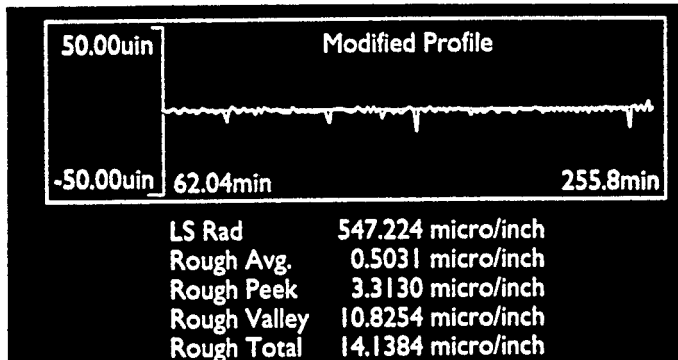


Figure 53 Surface finish for ceramic femoral head.

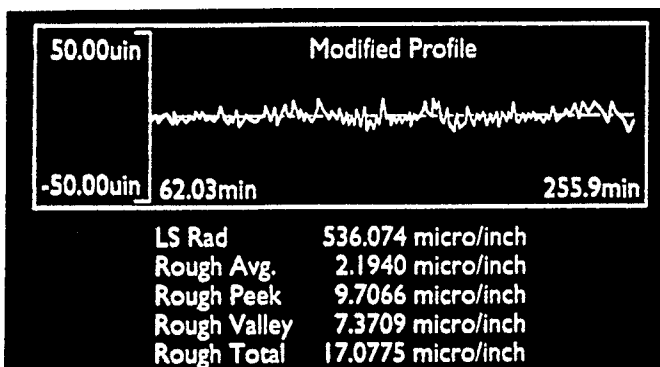


Figure 54 Surface finish for CoCr femoral head.

VII. NEAR FUTURE PRODUCTS

Ceramics have characteristics that are very desirable for use in sliding, rotating, and articulating bearing surfaces (Figs. 53 and 54). In addition to high compressive strength, they exhibit high wear and corrosion resistance with relatively low frictional movements. However, use of such ceramic materials in bearing systems has been inhibited because such materials are susceptible to fracture due to their relatively low tensile and shear strengths. This weakness is one reason why metal and/or polymeric materials have been used for many bearing surfaces. Compared to bearing ceramics, bearing metals and polymers typically have lower wear and corrosion resistance and higher frictional movements.

In bearing systems where ceramics have been used, their low tensile and shear strengths often force the adoption of costly design compromises. Thus, one design compromise has been to make the entire bearing component, rather than just a portion thereof, out of solid ceramic, effectively increasing the structural strength of the bearing surface. Such a solid ceramic bearing component can be larger and bulkier than its metal and/or polymeric counterpart.

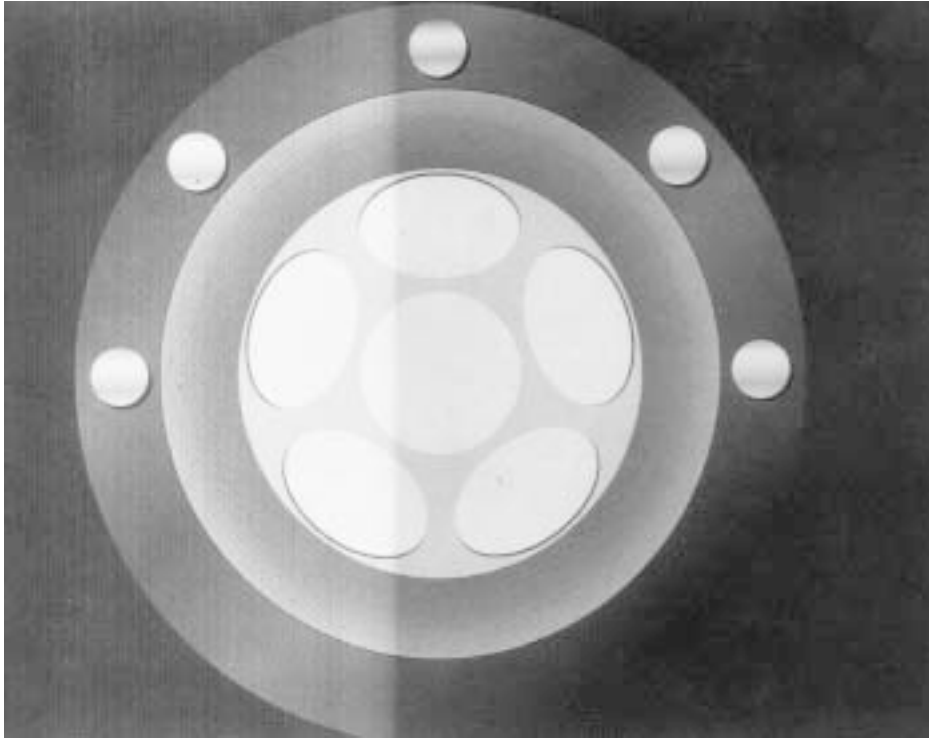


Figure 55 Segmented ceramic cup.

Making an entire bearing component such as the acetabular cup out of solid ceramic helps to compensate for the relatively poor tensile and shear strength typically found with ceramics. Also, because bearing ceramics are typically inflexible, additional manufacturing quality control of the geometry of both articular surfaces must be maintained in order to maximize the contact area between the two surfaces. If tight control is not maintained, point contact may develop between the bearing surfaces. As the contact area between two bearing surfaces decreases, the stress that is transmitted between the surfaces increases. This can result in greater wear and can increase the possibility of fracture of one or both surfaces [35,64].

In an attempt to address these problems, a segmented, ceramic bearing system has been developed [53] (Fig. 55). The segmented bearing system provides ceramic surfaces for mechanical bearings that would apply loads over a greater bearing area, resulting in reduced bearing stresses and would, in turn, reduce creep, wear, and the likelihood of fracture of the bearing surfaces.

The acetabular component is designed with ceramic articular segments that are backed and held in a predetermined pattern and configuration by either polyetheretherketone or polyethylene. Both of these materials have a lower elastic modulus than the segmented ceramic material. In addition, the polymeric material is reduced in height so that only the segmented ceramic material articulates with a ceramic femoral head.

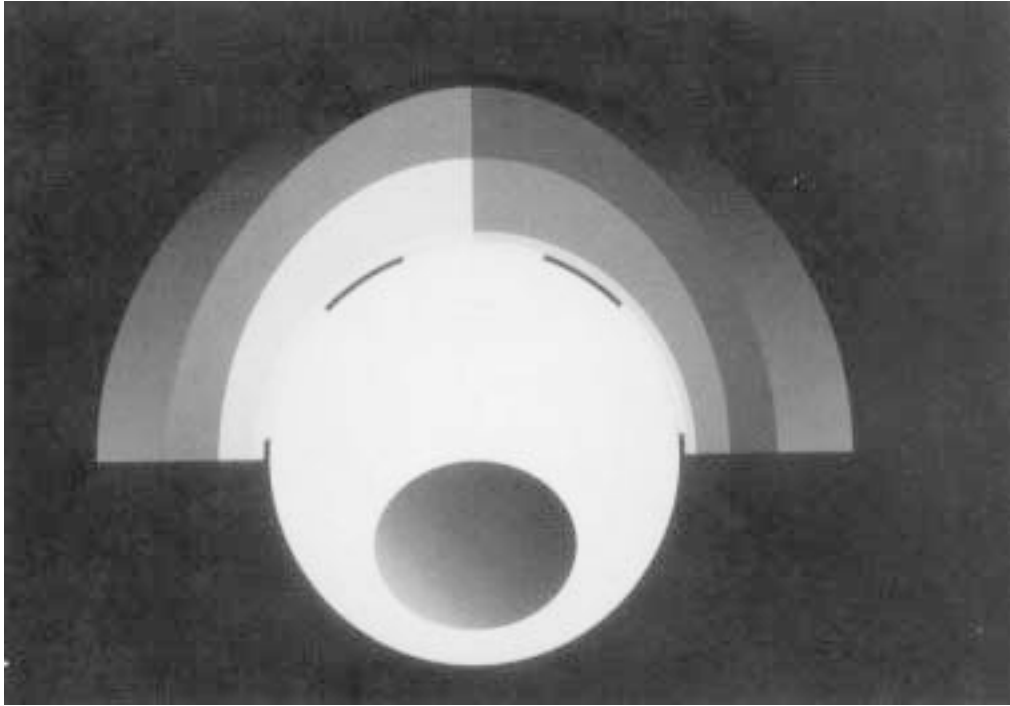


Figure 56 Lubrication channels in segmented cup.

Because of its resilience and lower elastic modulus, the polymeric material flexes as loads are transmitted between bearing surfaces while the shape of the surfaces of the segments remain relatively unchanged. This freedom of movement of the segments, under an applied load, allows for greater contact area between bearing surfaces because the segments as a group are able to conform to the geometry of the opposing bearing surface. Thus, rather than having the highly localized stress concentrations typically occurring in bearing systems, any applied load is shared by a number of segments, which results in lower stress being applied to the bearing surface and each segment.

An additional feature of this design is the formation of channels generated by locating the polymeric material slightly below the surface of the ceramic segments for lubrication and for allowing debris that finds its way into the bearing to either pass between the segments or be trapped into the polymeric material (Fig. 56).

This design allows for the segmented composite insert to be used with cemented hemispherical designs or cementless acetabular components. This highly innovative design provides for an alternative bearing surface that is cost-effective while it reduces or eliminates the generation of articulated polymeric or metallic debris. This design should have a tremendous positive effect on the overall reduction of particulate debris, resulting in increased longevity of total hip arthroplasty.

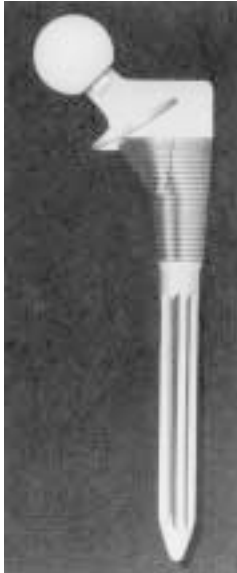


Figure 57 Unibody stem.

VIII. NEW DESIGN CONCEPT

In light of all that has been discussed, this section provides a review and current description of a new cementless total hip system. This system is a comprehensive system designed for primary and revision total hip replacement arthroplasty.

Patients face a variety of problems and solutions must be tailored to their individual needs.

A. Unibody Stem

This stem is a geometric design that features a proximal anterior flare that works in tandem with a 30° proximal conical flare collar. These two specific features aid in axial and torsional stability while providing increased surface geometry, resulting in increased compressive stress to the proximal femur. The neck shaft angle is 135° with 10° of anteversion. Lateral displacement of the femoral head is 40 mm.

The proximal conical collar allows for settling of the implant resulting in increased surface contact throughout the entire proximal stem geometry. In addition, the conical shape acts as a step in transferring hoop stress into compressive loads.

While providing improved fit and fill, the proximal conical shape provides a seal occluding wear debris from entering the femoral canal (Fig. 57).

B. Bibody Modular Stem

This stem's design incorporates a proximal, modular body that allows for correction of version, offset, and vertical height without disruption of the stem body. The two modular parts feature a double locking mechanism. The first is a trunion that engages in the stem

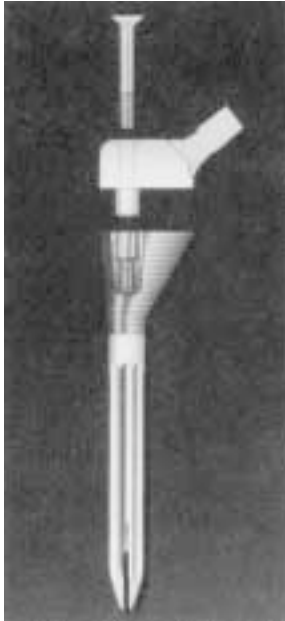


Figure 58 Bibody stem.

body by means of ratchet teeth. The specific design of these ratchet teeth allow for version adjustment in increments of 10°. The second locking feature is a set screw, which protects from disassembly.

The unique features of this design traps any debris that might be generated by the modularity and restricts this debris from interfacing with the host bone. In addition, once the bone has grown into the proximal porous area, polyethylene debris generated from normal wear is restricted from the distal stem area. Proximal bodies of different offsets, and vertical heights (Fig. 58) will allow for fine tuning hip joint biomechanics without removal of the stem.

IX STEM DESIGN FEATURES

A. Material

This stem will utilize high-strength titanium alloy. Manufacture will utilize forgings.

B. Taper Head Neck

The neck will accept a chrome-cobalt or ceramic articulation. The neck diameter has been designed to maximize range of motion as compared to other designs.

C. Offset

In order to improve biomechanical function, offset has been increased in comparison to competitive stems.

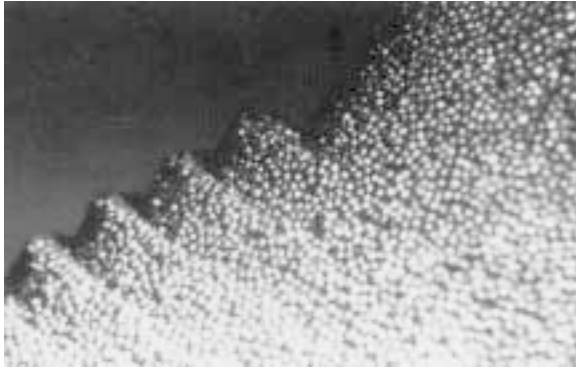


Figure 59 Stepped geometry with porous coating.

D. Surface Preparation

The stem is proximally porous coated utilizing a single, beaded porous coating of commercially pure titanium. This is sintered over a macrot textured design of horizontal steps, which helps to protect the beaded interface from shear forces and also helps in transferring hoop stresses to compression forces (Fig. 59). An additional option is a coating of HA which is plasma sprayed over the single, beaded porous surface. This single, beaded porous surface protects the HA in shear while also providing a backup for bony remodeling in case the HA is biochemically mobilized. Also, the nonporous surface has been treated with a proprietary microclean process that leaves a clean yet microrough surface [551].

E. Distal Bending Stiffness

The distal one third of the stem has been slotted in both the coronal and sagittal planes. These slots serve to reduce distal stem stiffness, allowing the stem to flex with the femur during normal daily activity. This feature has historically demonstrated reduced thigh pain (Fig. 60) [13]. In addition, it helps to reduce chances of intraoperative femoral fractures during stem insertion.



Figure 60 Bending forces.

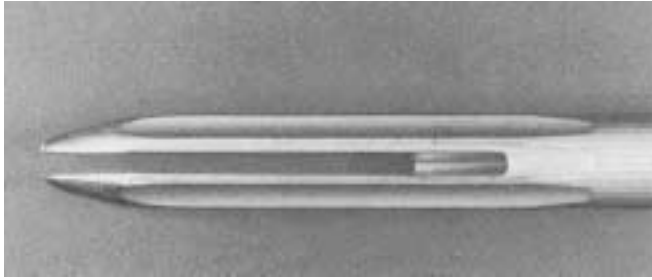


Figure 61 Distal slot design with flutes.

F. Distal Stability

To increase stem rotational stability, distal flutes have been incorporated into the stem design (Fig. 61). Rotational stability remains the primary concern of any femoral component.

G. Stem Tip

Bulleted geometry helps reduce distal point loading while creating a smooth transition zone for load transfer.

H. Instruments

Both stems - unibody and bibody - utilize the same instruments. Thus cost is reduced and there is also surgical ease in going from one stem to the next.

I. Acetabular Components

Two acetabular designs are offered in the system. The first is a standard ultra-high molecular weight (UHMWP) articulation that is compression molded to a hemispherical titanium alloy shell with CPT porous coating. This design will feature reduction in modularity with no angled offsets, which can result in decreased range of motion and can also result in increased chances of generation of particulate debris. The metal shell will feature peripheral screws for additional adjunct bony fixation, if indicated. This device will be indicated for, but not limited to the patient with a life expectancy of less than 15 years. It will also have significant cost savings over traditional systems.

The second design will have the same features; however, it will provide a ceramic articulation and will be indicated for, but not limited to the patient who has a life expectancy of more than 15 years.

X. SUMMARY

In view of the hundreds of thousands of total hip surgeries that have been performed since the surgery was introduced by Sir John Charnley over two decades ago, the small number of reported failures are not wholly unexpected. There is currently a great deal of debate over cement versus cementless indications. Initial concerns about wear rates of polyethylene have risen again due to the increased incidence of osteolysis induced by particulate debris.

Current methods of achieving implant fixation vary in concepts and techniques. Each method presents problems which must be addressed if cementless fixation is to survive long term. The justification for the continued use of cementless implants should be based on well-developed clinical and radiographic evidence.

In our opinion, everything possible should be done to reduce the generation of particulate debris. Continued research in surgical methodology, materials, and component design of total hip replacement can help to increase the longevity of implants and increase indications to a broader range of patients.

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