Design Considerations for Cementless Total Hip Arthroplasty

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Notes

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.

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.

Acetabular Consideration

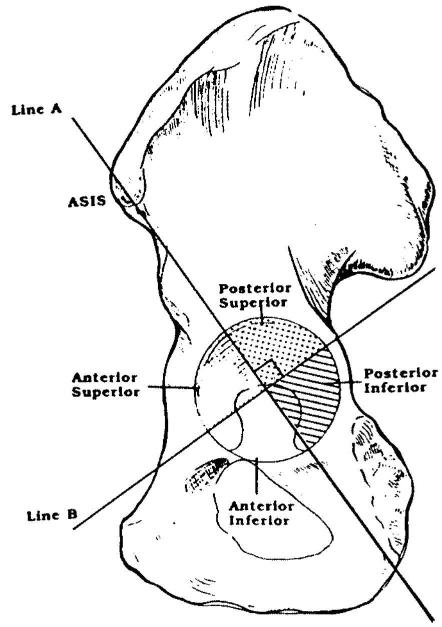
The hip joint is not a perfect ball-and-socket joint; the femoral head is oval in shape and the articular surface of the acetabulum is horseshoe shaped. The dome of the acetabulum, which has been considered a weight-bearing area, is in fact flexible. The horns of the acetabulum can thus close up and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

The acetabulum is generally spherical in shape 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 mm 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 [73,40]. 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.



Acetabulum quadrants.

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. 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 [51]. Each has encountered different degrees of success with various designs.

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.

B. Threaded Cups

Classification of Threaded Cups

This section discusses four classifications of threaded cups:

- Truncated cone
- Hemispherical ring
- Hemispherical shell with conical threads
- Hemispherical shell with spherical threads

C. Modular Acetabular Components

Two-piece, modular porous acetabular components have gained major market acceptance in total hip arthroplasty. 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. However, as

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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]. 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 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 [36,66].

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 [76].

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. 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.

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

Ideally, the bearing surface for most sliding, 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.
   - Polished interface.
   - 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.

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

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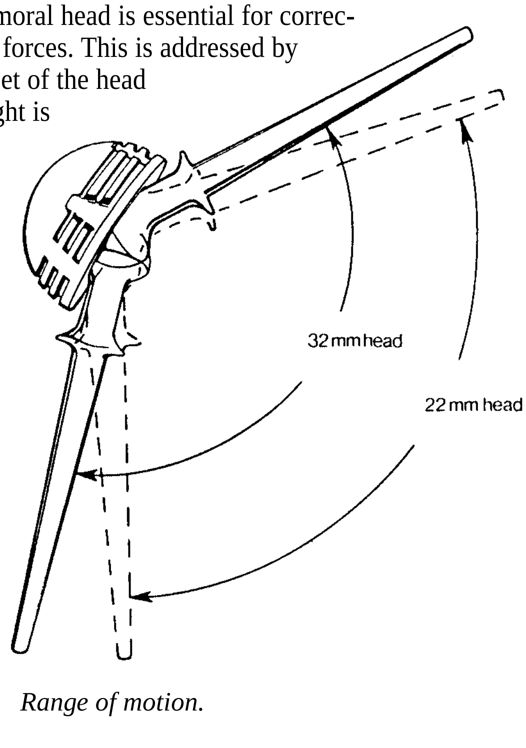
be considered: the neck shaft angle and the angle of anteversion. In addition to these two angles, the joint reaction force is affected by femoral head offset [28,65,37]. It is also important to remember that while static force is considerably greater than body weight, even greater force is generated 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 [31].

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. 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.

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. 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 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.



Range of motion.

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 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. However, the idea was not revisited until Pughs' work in 1981 led to the OmniFit™ design and his additional work that led to the 1984 S-ROM proximal sleeve design [62,63].

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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.

With cavitary and segmental bone damage it is difficult to achieve stability of the implant. 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 social economical 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 vs. anatomical and collar vs. collarless stem designs. In an attempt to appeal to both mentalities, newer geometric designs are emerging. These designs feature straight stems with anterior flares and anteverted necks.

C. Modular Stems

The concept of modularity is to provide for intraoperative customizing of fit and fill with each individual femur. There are a variety of modular designs available, from modular necks, proximal and distal sleeves, and mid-stem tapers. 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 need careful consideration in evaluating the long-term performance of modular interfaces [69].

D. Custom Stems

Customs offer great versatility; however, intraoperative customs reduce surface treatments such as hydroxyapatite (HA) or porous surfaces. 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.

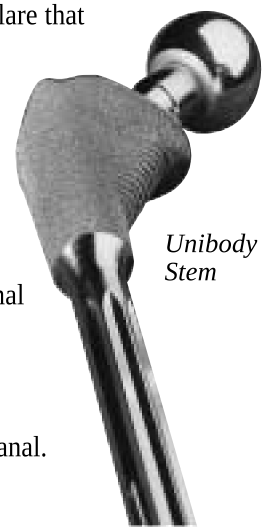
Obviously there is a need for all three types of implant modalities: unibody, modular, and customs (although these are not necessary with adequate modularity).

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.

Recommended Design Concept

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 antevision. Lateral displacement of the femoral head is 40 mm.



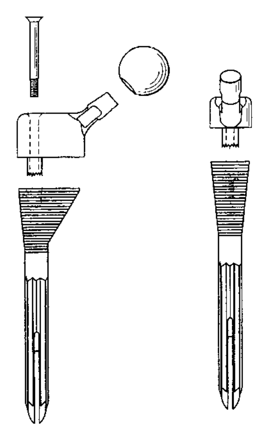
Unibody Stem

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.

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 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.



Bibody Modular Stem

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 will allow for fine tuning hip joint biomechanics without removal of the stem.

Stem Design Features

A. Material

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

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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, the proximal design features interchangeable modular necks. This feature allows for intraoperative adjustment of offset, leg length and ver- sion angle. This design could have a significant impact on reducing postoperative dislocations.

D. Surface Preparation

The stem is proximally porous coated utilizing a single, beaded porous coating of commercially pure titanium. This is sintered over a macrotextured design of horizontal steps, which helps to protect the beaded interface from shear forces and also helps in transferring hoop stresses to compression forces. 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 [55].

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 [13]. In addition, it helps to reduce chances of intraoperative femoral fractures during stem insertion.

F. Distal Stability

To increase stem rotational stability, distal flutes have been incorporated into the stem design. 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.

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.

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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