Custom-made Primary Total Hip Replacements

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Introduction

This article has three purposes: to establish the theoretical, experimental, anatomic, and clinical rationale for custom-made primary total hip replacements (THRs); to describe the design characteristics of the primary custom component that developed at our institution; and to present our preliminary clinical and radiographic results with this primary custom-made implant.

Well-cemented femoral components are, initially, rigidly fixed to bone. Concern has been expressed, however, about the long-term fixation of these implants in younger, more active, heavier patients\(^1\)\(^{-5}\) and the potential for long-term adverse bone remodeling.\(^3\)\(^,\)\(^4\)\(^,\)\(^10\)\(^{-22}\) Therefore, the goal of uncemented femoral implants should be to achieve rigid initial fixation, long-term durability, and positive bone remodeling.

Rationale for Custom-made THRs

Theoretical and experimental studies have shown that cementless femoral implants result in more normal stresses and strains in the proximal medial femur than cemented devices.\(^10\)\(^,\)\(^23\)\(^{-32}\) This more optimal load transfer is very dependent on accurate component fit. If the femoral stem is too large, a marked reduction in proximal stresses can occur. If the femoral stem is too small, excessive proximal stresses and strains can result.\(^5\)\(^,\)\(^8\)\(^,\)\(^27\)\(^,\)\(^33\)\(^{-35}\) The stress shielding predicted to occur when excessively large stems are inserted has, in fact, been observed clinically.\(^36\)\(^{-39}\)

Although vertical micromotion of an uncemented implant can be well controlled by an exactly fitting implant stem,\(^40\)\(^{-45}\) rotational micromotion has been more difficult to control\(^6\)\(^,\)\(^11\)\(^,\)\(^28\)\(^,\)\(^29\)\(^,\)\(^46\)\(^{-50}\) and probably requires intimate metaphyseal cortical bone/implant fit.\(^5\)\(^,\)\(^10\)\(^,\)\(^30\)\(^,\)\(^51\)

Anatomic studies have emphasized the wide variation in femoral diaphyseal geometries and the lack of relationship between diaphyseal and metaphyseal anatomy.\(^43\)\(^,\)\(^49\)\(^,\)\(^52\)\(^{-65}\) Clinical studies of uncemented implants\(^66\)\(^{-83}\) including our own,\(^84\) have borne out the predictions of theoretical, experimental, and anatomic work.

In 1984, we undertook a prospective study of two anatomic shaped, relatively short-stemmed implants—the collarless PCA and the collared APR. The results of implants fixed without cement were compared to those fixed with cement. Patients receiving uncemented implants were younger and more active than those receiving cemented devices. The implants were inserted using a surgical technique designed to fill the canal and achieve maximum metaphyseal cortical bone/implant contact.

The clinical results, as measured by annual Harris hip scores, were the same for cementless and cemented cases. However, a small but statistically significant number of patients with cementless implants had slight residual thigh pain that gradually resolved.

Although bone remodeling changes were more prominent around cementless implants, there was no association of these changes with clinical symptoms in this 2- to 4-year follow-up study. When we measured the extent to which we had achieved complete canal and proximal femoral fill, however, we found that we had been able to accurately reach cortex at the distal stem of the prostheses but had been much less successful in achieving proximal fill. Thus, one possible source of the mild, slowly resolving, occasionally recurrent thigh pain in our series was implant micromotion from inadequate fill and fit.

In addition, occasional cases were noted in which the shape of the femoral stem did not correspond to the shape of the femoral canal. In such situations, the tip of the component came into contact with the cortex of the femoral canal. This created a situation in which very concentrated loads against the femur could occur. These concentrated loads might be associated with episodes of recurrent thigh pain.

Due to our clinical experience, we were aware that the surgical technique necessary to insert conventionally

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made implants limited the accuracy with which these components fit within the femur. Preoperative planning for THR is important. This planning, when used to insert conventionally made implants, requires the use of radiographs, which have inherent limitations related to unpredictable magnification, variable penetration, the inability to control limb position in patients with severe arthritis of the hip, and the absence of cross-sectional views. These factors make planning for implant geometry, fit, and offset difficult if not impossible when radiographs are used.

The surgical technique used in inserting conventionally made implants also had the following inherent limitations that may explain the variable results reported by experienced surgeons using the same conventionally made implants:

- Sizing instruments, like reamers, are unreliable; for example, the mediolateral dimension of a femoral canal often differs from the anteroposterior dimension. When
reamers hitting cortex are used to size canals, they inevitably lead the surgeon to undersize them.
• The assessment of fit is subjective and inherently inaccurate. Although a surgeon may be able to assess implant fit at the opening of the femoral canal, the accuracy of fit below this point cannot be determined intraoperatively.
• The determination of implant stability is currently very imprecise.

The rationale for custom THR is, therefore, based on the following:
• Correct stress transfer requires exact fit.
• Variable femoral anatomy necessitates individually designed implants.
• Preoperative planning using computer reconstructions can be more precise than planning based on radiographs.
• The surgical techniques for inserting conventionally made uncemented implants and the methods available for assessing the stability of their fit are inherently inaccurate.

**Design Characteristics**

It is essential to realize that custom-made implants are not an exact anatomic fit. Customization means, and in fact requires, design priorities relating to implant geometry, materials, and biomechanical characteristics to be established. Custom-made implants can vary from case to case and surgeon to surgeon. It is important in assessing the results of these implants to be aware of the design priorities selected and to determine if these priorities stayed constant during the course of a particular clinical trial. The clinical and radiographic results of custom-made implants may vary with the design priorities chosen.
We selected design priorities based on our interpretation of currently available theoretical, experimental, anatomic, and clinical information and our surgical experience with uncemented total hip replacements. The stem length is established by using computer reconstructions to determine where the cortices become parallel and then extending the stem two to three canal diameters beyond that point. This results in relatively short stems and allows the insertion of an implant that fits tightly in the metaphysis. The contours of the stem match those of the femur. The diameter of the stem maximizes fit medially and anteroposteriorly. This may require reaming of up to 1 mm into the femoral cortex in the plane with the narrowest canal diameter.

Proximally, we designed the implant to conform to the medial arc of the femoral neck, to contact laterally at the base of the trochanter, and to be anatomically oriented with regard to anteversion and horizontal and vertical offset. We sought to fill the proximal femur maximally and to achieve intimate contact between implant and cortical bone (Fig 1).

The implants are made of titanium alloy and are proximally porous-coated medially, anteriorly, and posteriorly with pure titanium wire mesh (Fig 2). The modular femoral heads are cobalt-chrome. The implants are supplied with custom-made broaches, a 15% downsized starter broach, and a full-sized finishing broach.

**Results**

Between July 1987 and January 1989, 73 custom-made uncemented primary THR's were inserted at our institution. The indications have been similar to those used in our earlier experience with conventionally made uncemented THR. Follow up is too short to permit conclusions about the clinical and radiographic performance of these devices. Up to 1 year, the results were equivalent to previously used uncemented implants, though there were fewer patients with residual mild thigh pain.
The custom-made implants have achieved 20% greater canal fill with much less variation than conventionally made implants. Proximal fill has been substantially more complete. Subsidence of these custom-made implants has been very rare thus far. Custom-made implants have been particularly helpful and perhaps have their most logical current application in hips with significant deformity (Fig 1).

**Conclusion**

Theoretical, experimental, anatomic, and clinical studies have established the basis for custom-made THR's. The clinical and radiographic results of custom-made THR's, as with conventionally made implants, will differ according to the design priorities selected. Our results with the design priorities selected permit the preliminary conclusions that: preliminary clinical results are at least equivalent to those we achieve with conventionally made THR's; the custom-made implants fill the femur more completely and fit more accurately than conventionally made devices; the long-term consequences of these improvements in fit and fill are not yet known; and custom-made THR's are particularly appropriate for significant hip deformities.

**References**

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Figs 1G-II: AP, frog-lateral, and true lateral views of the custom implant designed and manufactured for a 39-year-old woman with degenerative arthritis secondary to hip dysplasia.


Fig 2: The custom implants are made of titanium-aluminum-vanadium alloy and are covered on the proximal medial, anterior, and posterior surfaces with titanium mesh.


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