Custom Cementless Femoral Stems in Total Hip Arthroplasty

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Obtaining appropriate prosthetic fit in cementless total hip arthroplasty can be challenging in cases with disparity between the femoral and metaphyseal diameters of the femur or cases of complex deformity. One solution has been to utilize a custom femoral component in total hip arthroplasty. The long-term results of this option with respect to femoral morphology are limited. This cohort was analyzed to determine the survivorship, functional results using Harris Hip Scores (HHSs), and complication rates using these implants. Survivorship and complications were evaluated based on the proximal femoral anatomy and severity of arthritis. The authors retrospectively reviewed 73 cases of custom femoral implants in total hip arthroplasties by a single surgeon. The average age of patients at index surgery was 58.06 years (range, 36.00–73.75 years). The mean follow-up was 8.59 years (range, 0.17–20.33 years) with a minimum of 2-year follow-up required for analysis of HHS data. There were 8 failures at a mean of 67.68 months (range, 2.04–135 months). The reasons for revision were infection (2), osteolysis (1), periprosthetic fracture (3), osteolysis and aseptic loosening (1), and polyethylene wear (1). The mean preoperative HHS was 55.38 (range, 31–90). The mean follow-up HHS was 93.10 (range, 38–100) with a mean improvement of 37.44 ($p < 0.0001$). Complications included infection (3), fracture (6), and dislocation (3). Preoperative Dorr classification A ($n = 44$), B ($n = 24$), and C ($n = 1$) and Kellgren–Lawrence grades I ($n = 0$), II ($n = 2$), III ($n = 7$), and IV ($n = 60$) were not predictive of failure or revision ($p = 0.45$, $p = 0.6$). There was a near significant association between Dorr classification B femur fractures requiring revision ($p < 0.053$). Kaplan–Meier predicted survivorship was 20.33 years with revision for any reason as the endpoint and total overall survivorship of 81.7%. Custom cementless femoral stems provide satisfactory survivorship and improvement in hip scores in a variety of patients undergoing cementless total hip arthroplasty. Fracture rates are higher in Dorr class B femurs. The level of evidence was IV.

Keywords
► hip
► arthroplasty
► custom

Investigation performed at University Hospitals Cleveland Medical Center.

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Tel: +1(212) 584-4662.
ISSN 2472-8446.
Use of cementless fixation of the femoral stem in total hip arthroplasty (THA) has been increasing in popularity and provided excellent clinical results.\textsuperscript{1,2} Obtaining proper femoral prosthesis fit in cases of prior fracture or complex morphologies can be challenging in younger patients especially those who have a disparity between a large metaphyseal and a narrow diaphyseal canal. Moreover, there is great variety in the anatomy of the proximal and diaphyseal femur across the population.\textsuperscript{3,4} These variations can present difficulties in matching the patients’ anatomy utilizing standard off-the-shelf implants. Techniques to accommodate complex proximal femoral anatomy include modularity, excess reaming, hybrid fixation, or even hip resurfacing. On the other hand, custom femoral implants based on preoperative imaging are commercially available and have been shown to provide good clinical results.\textsuperscript{5,6} These implants offer the theoretical advantage matching the patient’s unique anatomy without removing excess bone, modularity, or concerns about metal-on-metal hip resurfacing. In the literature to date, custom implants have not shown superior results to off-the-shelf components but are a viable alternative in complicated cases.

There have been some reports in the literature reporting clinical outcomes of several different custom stems with overall positive results in a variety of clinical situations.\textsuperscript{5–11} This study focused on the use of custom femoral implants designed based on preoperative computed tomography (CT) imaging. Long-term results of THA utilizing a CT-based custom femoral stem are favorable but limited to studies that often focus on congenital hip disease.\textsuperscript{12,13}

**Study Questions**

We sought to address the following questions: (1) What is the survivorship of custom uncemented femoral stems in THA? (2) Does THA with custom femoral stems improve pain and function measured by the Harris Hip Score (HHS)? (3) What is the complication rate utilizing these stems in THA? (4) Is there a difference in survivorship or complications based on the proximal femoral anatomy or severity of arthritis?

**Material and Methods**

**Study Design and Setting**

This study was a retrospective review of a total of 73 consecutive custom THAs. All surgeries were performed by a single surgeon (R.E.M.) at a single academic medical center from 1990 to 2012.

**Participants/Study Subjects/Demographics**

Patients undergoing custom THA were included if they had 2 years of minimum follow-up and complete HHS data. There were 43 men and 30 women. The mean age at time of surgery was 57.7 years (range, 25–73 years old). The primary diagnoses were osteoarthritis (n = 56), avascular necrosis (n = 8), developmental dysplasia of the hip (n = 4), Perthes disease (n = 2), ankylosing spondylitis (n = 2), and rheumatoid arthritis (n = 1). The indication for custom cementless femoral stems was cases in which there was a mismatch between the patient’s femoral metaphyseal and diaphyseal diameters that would be poorly accommodated by a standard prosthesis.

**Surgical Technique**

The custom patient-matched implant stems were designed preoperatively using CT imaging per the manufacturer’s protocol (Zimmer Biomet). The surgeon selected the following design parameters: stem diameter, length, anteversion, extent of porous coating, and femoral neck resection (\textsuperscript{\textcopyright} Fig. 1 and 2). Anteversion of the femoral prosthesis was selected.
to be 15 degrees of anteversion with respect to the femoral condyles unless the patient’s native anteversion was greater than 15 degrees. In these cases, the stem was designed to match the native femoral version. The acetabular components used were either Harris-Galante II or Trilogy (Zimmer Biomet).

The typical surgical technique is described briefly here. A posterolateral approach was utilized in all cases. A Steinmann Pin is placed just above the superior acetabulum and limb length is ascertained with a caliper from the pin to a point on the lateral femur. After careful dislocation of the femoral head, the offset from the center of the head to the tip of the greater trochanter is measured. Proximal femoral osteotomy is performed based on measurements from the prosthetic blueprint at a 45-degree angle. The acetabular component is then placed in standard press-fit fashion with appropriate placement with appropriate inclination and anteversion. The goal orientation of the cup was 40 degrees of abduction and 20 degrees of anteversion.

Attention is then focused on the proximal femur. The length of the femoral neck cut is measured and must be identical to that of the computer modeling (Fig. 2). The lateral base of the femoral neck is identified by clearing the soft tissue from this area and removed to the base of the greater trochanter. The canal is opened with a T-handled reamer and progressive flexible reaming is accomplished to the prosthetic design diameter. The depth of reaming is measured with respect to the custom broach. Provisional broaches are then inserted as calculated from the design blueprint of the implant. The custom broach is then utilized to complete the broaching process. The broach should be completely seated based on the blueprint measurement from the base of the lesser trochanter.

The custom implant is then impacted into place and should achieve a rigid press fit over the last centimeter of impaction with both axial and rotational stability. Measurements should be made from the lesser trochanter to the top of the porous coating on the prosthesis and these should correspond to the blueprint for the prosthesis. After satisfactory trialing, the appropriate components are placed and rechecked for stability. All patients in this study received a femoral head from 28 to 36 mm. The posterior capsule and external rotators are repaired using transosseous drill holes. The wound is closed in layers with subcutaneous absorbable sutures and staples.

Aftercare
Postoperatively, patients received inpatient physical and occupational therapy. Patients were limited to 50% weight bearing and posterior hip precautions for 6 weeks. Deep venous thrombosis chemoprophylaxis consisted of warfarin.

Study Outcomes
Survivorship with revision for any reason as the endpoint was the principal outcome measure. We also evaluated pre- and postoperative HHSs. Preoperative radiographs were utilized to determine Dorr classification and Kellgren-Lawrence grades.

Statistical Analysis
A Kaplan–Meier survivorship curve was used to determine overall survivorship of the femoral stem, acetabular component, and both components. The preoperative and postoperative HHSs were compared with a paired t-test. A Cox proportional hazards model was used to correlate Dorr classification and Kellgren-Lawrence grades with survivorship.

Results
When considering just the femoral stem revisions, the survivorship was 97.3%. This was higher than the acetabular component survivorship of 96.0 and 94.2% for both components (including liner exchanges for polyethylene wear). The total construct survivorship of custom uncemented femoral stems in THA was 89.0% with a mean follow-up of 8.59 years (range, 0.17–20.33 years).

Early failures were included to prevent exclusion bias, but their later HHSs were not included. There were 8 failures requiring revision at a mean of 67.68 months (range, 2.04–135 months). The indications for revision were infection (2), osteolysis (1), periprosthetic fracture (3), osteolysis and aseptic loosening (1), and polyethylene wear (1). The Kaplan–Meier predicted survivorship was 20.33 years using revision for any reason as the endpoint with an overall survivorship of 81.7% (Fig. 3). Table 1 features the diagnoses and time to failure of these cases.

Harris hip scores were improved with THA. The mean preoperative HHS was 55.38 (range, 31–90). The mean follow-up HHS was 93.10 (range, 38–100) with a mean improvement of 37.44 (p < 0.0001). Complications developed in 12 patients with an overall rate of 16.4%. The most common was fracture (6 patients), followed by infection (3) and dislocation (3). The six fractures were composed of one acetabular fracture while the other five were peri-prosthetic femur fractures. Of the femoral fractures, two occurred at a mean of 154 months postop and were treated...
nonoperatively. There were three Vancouver B2 periprosthetic fractures occurring at 2, 3, and 111 months postoperatively treated with stem revision and open reduction and internal fixation of the fracture. One dislocation was due to liner wear and was treated with head and liner exchange at approximately 19 years postoperatively. The other two dislocations were treated with closed reduction without further instability. All three cases of infection occurred at 4, 44, and 67 months postoperatively of which two were revised.

The preoperative Dorr classification was composed of types A (n = 44), B (n = 24), and C (n = 1). The Dorr class was not found to be predictive of failure (p = 0.45). However, there was a significant association with postoperative fractures with type B femurs (p < 0.033). There was a nearly significant association with type B femurs even when we included only the 3 cases that resulted in reoperation (p < 0.053). The severity of arthritis as graded by the Kellgren-Lawrence grades were I (n = 0), II (n = 2), III (n = 7), and IV (n = 60). These grades were not significantly associated with failure or revision (p = 0.6).

Discussion

Cementless femoral stems have become the most commonly used design in THA. Lehil and Bozic reported that 94% of stems were cementless in 2012 compared with 49.6% in 2001 using the Orthopaedic Research Network data. Despite this widespread utilization, the ideal stem design, geometry, and ingrowth surface for these components have yet to be proven. Given the wide variation in femoral anatomy across the population, there may be a role for custom femoral stems to provide a durable and stable reconstruction.

Custom femoral stems have been demonstrated to be applicable in complex primary cases such as prior fracture or underlying Perthes disease. This study was performed to determine: the survivorship of custom uncemented femoral stems in THA; the improvement in HHS; the complication rate; and the relationship of survivorship and complications based on the proximal femoral anatomy and severity of arthritis.

This study was a retrospective review and therefore has inherent limitations. Since this is a single-surgeon and single femoral implant design cohort, our results may not be applicable to all custom implants available. The acetabular component and bearing couple was not consistent throughout the study group which may have introduced uncontrolled variables with respect to overall survivorship. The lack of a control group prevents us from comparing our results to a similar off-the-shelf implant. Radiographic parameters including femoral anteversion and native offset measured preoperatively were also not available for review. This prevented detailed analysis of preoperative planning of the stem parameters.

With respect to durability of the stem, the Kaplan–Meier predicted survivorship of 20.33 years using revision for any reason as the endpoint as well as overall survivorship of 81.7% compares unfavorably with a large study by Colen et al who reported 95.5% 20-year survivorship of 1,659 primary THAs utilizing an intraoperative manufactured prosthesis. However, when considering femoral stemmed failures in our investigation, the survivorship rose to 97.3% for the same time frame with a mean of 118 months. These results are similar to results of several other custom stems with a variety of indications and cohort sizes.

Our results demonstrate significantly improved pain and function after custom cementless THA. Mean preoperative HHS was 55.38 with a mean follow-up of 93.10 for a mean improvement of 37.44 (p < 0.0001). These results are similar to other reported groups who have reported similar improvements with a variety of cementless stem geometries.

We observed 12 total complications in this group for an overall rate of 16.4%. The most common was fracture (6 patients), followed by infection (3) and dislocation (3). One fracture was of the acetabulum while the other five were periprosthetic femur fractures of which three were operative. Dorr class B femurs were found to have a statistically significant association with postoperative fractures (p < 0.033). Of note, the association with fracture was nearly

<table>
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<th>Diagnosis</th>
<th>Number</th>
<th>Time to failure (mo)</th>
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<td>Infection</td>
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<td>4</td>
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<tr>
<td>Osteolysis</td>
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<td>Osteolysis and aseptic loosening</td>
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<td>132</td>
</tr>
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<td>Polyethylene wear</td>
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<td>135</td>
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<td>2</td>
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significant when we limited the number to cases which resulted in reoperation ($p < 0.053$). Our postoperative fracture rate is slightly higher than many shorter term follow-up studies, but these groups were comprised of younger patient populations. Of the three that were revised, two were early at 2 and 3 months postoperatively and one occurred late at 111 months postoperatively. We had no intraoperative fractures which was also reported by Flecher et al and Chow et al.\textsuperscript{8,10} Benum and Aamodt reported a 1% intraoperative fracture rate. The association between Dorr type B femora and fracture of the femur was a minor finding of this study. The fractures among Dorr B cases in this study were of borderline significance considering that only two of the three cases occurred within 90 days of surgery. Like off-the-shelf implants, custom cementless THA may be complicated by fractures.

Both Dorr types B and C are vulnerable to early fracture after THA or hemiarthroplasty.\textsuperscript{17,18} We attribute the lack of fractures in Dorr type C bone because of our preference for a cemented stem in these cases. Therefore, there was only one Dorr C femur in the study. Three patients in our cohort had postoperative dislocations (4.1%). One dislocation was due to liner wear and was treated with head and liner exchange at approximately 19 years postoperatively. The other two dislocations occurred within 2 years of surgery and were treated with closed reduction without further instability. Other groups have reported similar dislocation rates ranging from 0 to 3.3%.\textsuperscript{5,8,10} The use of the Dorr class in planning custom cementless THA may not be intuitive in cases of abnormal anatomy illustrated in \textsuperscript{-Fig. 1}. We hypothesized that femoral anatomy (Dorr class) and severity of arthritis may predict survivorship. However, Dorr class and Kellgren–Lawrence grades did not prognosticate survivorship ($p = 0.43$ and $p = 0.21$, respectively).

**Conclusion**

Total hip arthroplasty utilizing CT-based custom cementless stems have satisfactory overall survivorship and excellent femoral sided survivorship. Fracture is the most common complication with Dorr type B femurs.

**Conflicts of Interest**

None.

**References**